

US3192734 (Prod: Quality of Life Medical and Research Center - Hunt - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:38:11

All time stamps listed in this document are displayed in GMT

US3192734

Form: Participant Creation

Data signed: (b) (4) 03 Apr 2021 14:32:43

Generated On: 09 Jun 2021 15:38:11

[Participant ID](#)

US3192734

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

US3192734

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 03:28:23

Generated On: 09 Jun 2021 15:38:11

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 04 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 | SCRN |

US3192734

Folder: Screening

Form: Demographics

Data signed: (b) (4) 14 Feb 2021 03:28:21

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| Date of Birth (MMM yyyy) | (b) (6) 1962 |
| Age | 58 |
| Age Units | YEARS |
| Age (Derived) | 58 |
| Sex | Female <input checked="" type="radio"/> Male <input type="radio"/> |
| Ethnicity | Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/> |
| Race (Check All That Apply) | |
| White | 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 |

US3192734

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 14 Feb 2021 03:28:21

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 14 Feb 2021 03:28:22

Generated On: 09 Jun 2021 15:38:11

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3192734

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 14 Feb 2021 03:28:22

Generated On: 09 Jun 2021 15:38:11

Were any significant conditions reported?

Yes ☒

No ☐

US3192734

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 08 Apr 2021 12:37:13

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| Condition | SINUS TACHYCARDIA |
| Start date (dd MMM yyyy) | UN JUN 2019 |
| 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) | JUN 2019 |
| Start Year (derived) | 2019 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

US3192734

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 08 Apr 2021 12:37:13

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| Condition | ANXIETY |
| Start date (dd MMM yyyy) | UN MAR 2020 |
| 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) | MAR 2020 |
| Start Year (derived) | 2020 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

US3192734

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 08 Apr 2021 12:37:13

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| Condition | DEPRESSION |
| Start date (dd MMM yyyy) | UN MAR 2020 |
| 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) | MAR 2020 |
| Start Year (derived) | 2020 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

US3192734

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 08 Apr 2021 12:37:13

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| Condition | OBSTRUCTIVE AIRWAY LIMITATION/CHRONIC PULMONARY FIBROSIS |
| Start date (dd MMM yyyy) | UN JUN 1999 |
| 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) | JUN 1999 |
| Start Year (derived) | 1999 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

US3192734

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 08 Apr 2021 12:37:13

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| Condition | BILATERAL HEARING LOSS |
| Start date (dd MMM yyyy) | UN OCT 2019 |
| 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) | OCT 2019 |
| Start Year (derived) | 2019 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

US3192734

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 08 Apr 2021 12:37:13

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| Condition | HYPERTENSION |
| Start date (dd MMM yyyy) | UN SEP 2019 |
| 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) | SEP 2019 |
| Start Year (derived) | 2019 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

US3192734

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 08 Apr 2021 12:37:13

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| Condition | FIBROIDS |
| Start date (dd MMM yyyy) | UN UNK 2012 |
| 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 2012 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2012 |
| Start Year (derived) | 2012 |
| Stop Month and Year (derived) | JAN 2012 |
| Stop Year (derived) | 2012 |

US3192734

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 08 Apr 2021 12:37:13

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| Condition | GALLSTONES |
| Start date (dd MMM yyyy) | UN UNK 2001 |
| 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 2001 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2001 |
| Start Year (derived) | 2001 |
| Stop Month and Year (derived) | JAN 2001 |
| Stop Year (derived) | 2001 |

US3192734

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 08 Apr 2021 12:37:13

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| Condition | LEFT BREAST CANCER |
| Start date (dd MMM yyyy) | UN UNK 2008 |
| 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 2008 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2008 |
| Start Year (derived) | 2008 |
| Stop Month and Year (derived) | JAN 2008 |
| Stop Year (derived) | 2008 |

US3192734

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 08 Apr 2021 12:37:13

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| Condition | HODGKIN'S LYMPHOMA |
| Start date (dd MMM yyyy) | UN UNK 1999 |
| 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 1999 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1999 |
| Start Year (derived) | 1999 |
| Stop Month and Year (derived) | JAN 1999 |
| Stop Year (derived) | 1999 |

US3192734

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 08 Apr 2021 12:37:13

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| Condition | LEFT MASTECTOMY |
| Start date (dd MMM yyyy) | UN UNK 2008 |
| 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 2008 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2008 |
| Start Year (derived) | 2008 |
| Stop Month and Year (derived) | JAN 2008 |
| Stop Year (derived) | 2008 |

US3192734

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 08 Apr 2021 12:37:13

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| Condition | HYSTERECTOMY |
| Start date (dd MMM yyyy) | UN UNK 2012 |
| 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 2012 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2012 |
| Start Year (derived) | 2012 |
| Stop Month and Year (derived) | JAN 2012 |
| Stop Year (derived) | 2012 |

US3192734

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 08 Apr 2021 12:37:13

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| Condition | CHOLECYSTECTOMY |
| Start date (dd MMM yyyy) | UN UNK 2001 |
| 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 2001 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2001 |
| Start Year (derived) | 2001 |
| Stop Month and Year (derived) | JAN 2001 |
| Stop Year (derived) | 2001 |

US3192734

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 08 Apr 2021 12:37:13

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| Condition | INSOMNIA |
| 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) | _____ |

US3192734

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 08 Apr 2021 12:37:13

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| Condition | RADIATION FOR LYMPHOMA |
| Start date (dd MMM yyyy) | UN UNK 1999 |
| 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 1999 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1999 |
| Start Year (derived) | 1999 |
| Stop Month and Year (derived) | JAN 1999 |
| Stop Year (derived) | 1999 |

US3192734

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 14 Feb 2021 03:28:23

Generated On: 09 Jun 2021 15:38:11

| | |
|-------------------------------------|--------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 4 OCT 2020 |
| Time of assessment (00:00-23:59) | 14:39 (24 HR) |
| Vital Signs Date and Time (derived) | 4 OCT 2020 14:39 |
| Height (xxx.x) | 67 in |
| Weight (xxx.x) | 174.8 lb |
| BMI (xxx.x) | 27.43479 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) | |

US3192734

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 14 Feb 2021 03:28:22

Generated On: 09 Jun 2021 15:38:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 OCT 2020

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

US3192734

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 14 Feb 2021 03:28:21

Generated On: 09 Jun 2021 15:38:11

Date of assessment (dd MMM yyyy) 4 OCT 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) UN UNK 2012

Date of surgery unknown False

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

Date of last menstruation unknown False

US3192734

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 14 Feb 2021 03:28:22

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 14 Feb 2021 03:28:22

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 03:28:23

Generated On: 09 Jun 2021 15:38:11

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 4 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 | VISIT1 |

US3192734

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 14 Feb 2021 03:28:23

Generated On: 09 Jun 2021 15:38:11

What was the date of randomization? (dd MMM yyyy) 04 OCT 2020

What was the participant's randomization number? 146890

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

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

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

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

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

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

Liver Disease Yes ☐
 No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐
 No ☒

US3192734

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 14 Feb 2021 03:28:23

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 14 Feb 2021 03:28:23

Generated On: 09 Jun 2021 15:38:11

| | |
|-------------------------------------|--|
| 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) | 4 OCT 2020 |
| Time of assessment (00:00-23:59) | 12:14 (24 HR) |
| Vital Signs Date and Time (derived) | 4 OCT 2020 12:14 |
| Temperature (xxx.x) | 98.9 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 67 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 121 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 82 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3192734

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 14 Feb 2021 03:28:23

Generated On: 09 Jun 2021 15:38:11

| | |
|-------------------------------------|---|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| Timepoint | Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/> |
| Were vital signs assessed? | Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> |
| Date of assessment (dd MMM yyyy) | 4 OCT 2020 |
| Time of assessment (00:00-23:59) | 14:39 (24 HR) |
| Vital Signs Date and Time (derived) | 4 OCT 2020 14:39 |
| Temperature (xxx.x) | 97.8 F |
| Route of measurement | Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/> |
| If Other, specify | |
| Pulse (xxx) | 73 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 10 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 114 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 78 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3192734

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 14 Feb 2021 03:28:23

Generated On: 09 Jun 2021 15:38:11

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.

US3192734

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 14 Feb 2021 03:28:23

Generated On: 09 Jun 2021 15:38:11

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) 4 OCT 2020

What was the treatment time? (00:00-23:59) 14:09 (24 HR)

Treatment Date and Time (derived) 4 OCT 2020 14:09

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

US3192734

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Feb 2021 03:28:23

Generated On: 09 Jun 2021 15:38:11

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 4 OCT 2020 |
| Collection time (00:00-23:59) | 13:59 (24 HR) |
| Collection date and time (derived) | 4 OCT 2020 13:59 |

US3192734

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 14 Feb 2021 03:28:23

Generated On: 09 Jun 2021 15:38:11

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 4 OCT 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 13:55 | 4 OCT 2020 13:55 |
| Nasopharyngeal Swab 2 | No | | |

US3192734

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 03:28:23

Generated On: 09 Jun 2021 15:38:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 OCT 2020 14:48

PC Open Date & Time

04 OCT 2020 14:29

PC Close Date & Time

04 OCT 2020 16:59

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

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 96.9 °F

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

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 04 OCT 2020 21:32 |
| PC Open Date & Time | 04 OCT 2020 17:54 |
| PC Close Date & Time | 05 OCT 2020 11:59 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:38:11

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

96.5 °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 OCT 2020 21:40

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:38:11

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

96.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 OCT 2020 21:58

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:38:11

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 OCT 2020 19:54

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:38:11

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

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 OCT 2020 22:20

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:38:11

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

97.7 °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

09 OCT 2020 17:53

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °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

10 OCT 2020 22:00

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 OCT 2020 14:49

PC Open Date & Time

04 OCT 2020 14:29

PC Close Date & Time

04 OCT 2020 16:59

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

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

04 OCT 2020 21:33

PC Open Date & Time

04 OCT 2020 17:54

PC Close Date & Time

05 OCT 2020 11:59

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:38:11

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

05 OCT 2020 21:41

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:38:11

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

06 OCT 2020 21:58

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:38:11

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

07 OCT 2020 19:54

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:38:11

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

08 OCT 2020 22:20

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:38:11

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

09 OCT 2020 17:54

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:38:11

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

10 OCT 2020 22:00

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

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 ☐

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 04 OCT 2020 14:49 |
| PC Open Date & Time | 04 OCT 2020 14:29 |
| PC Close Date & Time | 04 OCT 2020 16:59 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

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 ☐

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 04 OCT 2020 21:33 |
| PC Open Date & Time | 04 OCT 2020 17:54 |
| PC Close Date & Time | 05 OCT 2020 11:59 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

57 of 3379

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:11

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 05 OCT 2020 21:41 |
| PC Open Date & Time | 05 OCT 2020 12:00 |
| PC Close Date & Time | 06 OCT 2020 11:59 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

59 of 3379

EAB) (1725)

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:11

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 06 OCT 2020 21:58 |
| PC Open Date & Time | 06 OCT 2020 12:00 |
| PC Close Date & Time | 07 OCT 2020 11:59 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

61 of 3379

EAB) (1725)

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:11

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 07 OCT 2020 19:55 |
| PC Open Date & Time | 07 OCT 2020 12:00 |
| PC Close Date & Time | 08 OCT 2020 11:59 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:11

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 ☒

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:11

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 08 OCT 2020 22:21 |
| PC Open Date & Time | 08 OCT 2020 12:00 |
| PC Close Date & Time | 09 OCT 2020 11:59 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:11

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)

65 of 3379

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:11

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 09 OCT 2020 17:54 |
| PC Open Date & Time | 09 OCT 2020 12:00 |
| PC Close Date & Time | 10 OCT 2020 11:59 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:11

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

67 of 3379

EAB) (1725)

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:11

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 10 OCT 2020 22:00 |
| PC Open Date & Time | 10 OCT 2020 12:00 |
| PC Close Date & Time | 11 OCT 2020 11:59 |

US3192734

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 03:28:21

Generated On: 09 Jun 2021 15:38:11

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3192734

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 03:28:21

Generated On: 09 Jun 2021 15:38:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192734

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 04:11:47

Generated On: 09 Jun 2021 15:38:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192734

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 04:11:47

Generated On: 09 Jun 2021 15:38:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192734

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 03:28:21

Generated On: 09 Jun 2021 15:38:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192734

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 03:28:21

Generated On: 09 Jun 2021 15:38:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192734

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 03:28:23

Generated On: 09 Jun 2021 15:38:11

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 2 NOV 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT2 |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 14 Feb 2021 03:28:23

Generated On: 09 Jun 2021 15:38:11

| | |
|-------------------------------------|---|
| 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 NOV 2020 |
| Time of assessment (00:00-23:59) | 10:44 (24 HR) |
| Vital Signs Date and Time (derived) | 2 NOV 2020 10:44 |
| Temperature (xxx.x) | 96.9 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 70 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 110 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 67 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 14 Feb 2021 03:28:23

Generated On: 09 Jun 2021 15:38:11

| | |
|-------------------------------------|--|
| 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 NOV 2020 |
| Time of assessment (00:00-23:59) | 13:07 (24 HR) |
| Vital Signs Date and Time (derived) | 2 NOV 2020 13:07 |
| Temperature (xxx.x) | 97.4 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 64 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 115 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 71 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 14 Feb 2021 03:28:23

Generated On: 09 Jun 2021 15:38:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 NOV 2020

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

US3192734

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 14 Feb 2021 03:28:23

Generated On: 09 Jun 2021 15:38:11

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 NOV 2020

What was the treatment time? (00:00-23:59) 12:37 (24 HR)

Treatment Date and Time (derived) 2 NOV 2020 12:37

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

US3192734

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Feb 2021 03:28:23

Generated On: 09 Jun 2021 15:38:11

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 2 NOV 2020 |
| Collection time (00:00-23:59) | 11:13 (24 HR) |
| Collection date and time (derived) | 2 NOV 2020 11:13 |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 14 Feb 2021 03:28:23

Generated On: 09 Jun 2021 15:38:11

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 2 NOV 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 11:18 | 2 NOV 2020 11:18 |
| Nasopharyngeal Swab 2 | No | | |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 03:28:23

Generated On: 09 Jun 2021 15:38:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

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

97.4 °F

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

Yes ☐
No ☒

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

PC Time Stamp

02 NOV 2020 13:03

PC Open Date & Time

02 NOV 2020 12:57

PC Close Date & Time

02 NOV 2020 15:27

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

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 96.5 °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 | 02 NOV 2020 20:42 |
| PC Open Date & Time | 02 NOV 2020 16:22 |
| PC Close Date & Time | 03 NOV 2020 11:59 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:38:11

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

96.5 °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

04 NOV 2020 07:05

PC Open Date & Time

03 NOV 2020 12:00

PC Close Date & Time

04 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:38:11

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

98.7 °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

05 NOV 2020 04:17

PC Open Date & Time

04 NOV 2020 12:00

PC Close Date & Time

05 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:38:11

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 <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Please record your TEMPERATURE in °F | 98.5 °F |
| Was any MEDICATION TAKEN today for pain or fever? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |

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 | 05 NOV 2020 18:11 |
| PC Open Date & Time | 05 NOV 2020 12:00 |
| PC Close Date & Time | 06 NOV 2020 11:59 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:38:11

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

95.4 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

07 NOV 2020 07:08

PC Open Date & Time

06 NOV 2020 12:00

PC Close Date & Time

07 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:38:11

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

97.7 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

07 NOV 2020 22:27

PC Open Date & Time

07 NOV 2020 12:00

PC Close Date & Time

08 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:38:11

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

99.0 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

08 NOV 2020 19:06

PC Open Date & Time

08 NOV 2020 12:00

PC Close Date & Time

09 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 8

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.4 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

10 NOV 2020 06:34

PC Open Date & Time

09 NOV 2020 12:00

PC Close Date & Time

10 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 9

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 ☒

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

11 NOV 2020 08:43

PC Open Date & Time

10 NOV 2020 12:00

PC Close Date & Time

11 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 10

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 <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Please record your TEMPERATURE in °F | 97.5 °F |
| Was any MEDICATION TAKEN today for pain or fever? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |

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 | 11 NOV 2020 21:03 |
| PC Open Date & Time | 11 NOV 2020 12:00 |
| PC Close Date & Time | 12 NOV 2020 11:59 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 11

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

12 NOV 2020 21:53

PC Open Date & Time

12 NOV 2020 12:00

PC Close Date & Time

13 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

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 NOV 2020 13:04

PC Open Date & Time

02 NOV 2020 12:57

PC Close Date & Time

02 NOV 2020 15:27

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

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 NOV 2020 20:42

PC Open Date & Time

02 NOV 2020 16:22

PC Close Date & Time

03 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:38:11

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

04 NOV 2020 07:05

PC Open Date & Time

03 NOV 2020 12:00

PC Close Date & Time

04 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:38:11

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 NOV 2020 04:17

PC Open Date & Time

04 NOV 2020 12:00

PC Close Date & Time

05 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 NOV 2020 18:11

PC Open Date & Time

05 NOV 2020 12:00

PC Close Date & Time

06 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:38:11

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 NOV 2020 07:09

PC Open Date & Time

06 NOV 2020 12:00

PC Close Date & Time

07 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:38:11

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 NOV 2020 22:28

PC Open Date & Time

07 NOV 2020 12:00

PC Close Date & Time

08 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:38:11

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 NOV 2020 19:06

PC Open Date & Time

08 NOV 2020 12:00

PC Close Date & Time

09 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

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 ☐

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 02 NOV 2020 13:04 |
| PC Open Date & Time | 02 NOV 2020 12:57 |
| PC Close Date & Time | 02 NOV 2020 15:27 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

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 ☐

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 02 NOV 2020 20:43 |
| PC Open Date & Time | 02 NOV 2020 16:22 |
| PC Close Date & Time | 03 NOV 2020 11:59 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

107 of 3379

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:11

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 04 NOV 2020 07:06 |
| PC Open Date & Time | 03 NOV 2020 12:00 |
| PC Close Date & Time | 04 NOV 2020 11:59 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

109 of 3379

EAB) (1725)

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:11

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 05 NOV 2020 04:18 |
| PC Open Date & Time | 04 NOV 2020 12:00 |
| PC Close Date & Time | 05 NOV 2020 11:59 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☒

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☒

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☒

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

111 of 3379

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:11

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 05 NOV 2020 18:12 |
| PC Open Date & Time | 05 NOV 2020 12:00 |
| PC Close Date & Time | 06 NOV 2020 11:59 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☒

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☒

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☒

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

113 of 3379

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:11

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)

115 of 3379

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:11

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 07 NOV 2020 22:29 |
| PC Open Date & Time | 07 NOV 2020 12:00 |
| PC Close Date & Time | 08 NOV 2020 11:59 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:11

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

117 of 3379

EAB) (1725)

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:11

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 08 NOV 2020 19:07 |
| PC Open Date & Time | 08 NOV 2020 12:00 |
| PC Close Date & Time | 09 NOV 2020 11:59 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp

10 NOV 2020 06:35

PC Open Date & Time

09 NOV 2020 12:00

PC Close Date & Time

10 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp 11 NOV 2020 08:43

PC Open Date & Time 10 NOV 2020 12:00

PC Close Date & Time 11 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

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 ☐

PC Time Stamp

11 NOV 2020 21:03

PC Open Date & Time

11 NOV 2020 12:00

PC Close Date & Time

12 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp 12 NOV 2020 21:53

PC Open Date & Time 12 NOV 2020 12:00

PC Close Date & Time 13 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(12)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your

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 ☐

PC Time Stamp 13 NOV 2020 21:52

PC Open Date & Time 13 NOV 2020 12:00

PC Close Date & Time 14 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(13)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp

15 NOV 2020 07:15

PC Open Date & Time

14 NOV 2020 12:00

PC Close Date & Time

15 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(14)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp

PC Open Date & Time

15 NOV 2020 12:00

PC Close Date & Time

16 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(15)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp

16 NOV 2020 12:09

PC Open Date & Time

16 NOV 2020 12:00

PC Close Date & Time

17 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(16)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 16

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp

PC Open Date & Time

17 NOV 2020 12:00

PC Close Date & Time

18 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(17)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 17

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp

PC Open Date & Time

18 NOV 2020 12:00

PC Close Date & Time

19 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:38:11

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

10 NOV 2020 06:35

PC Open Date & Time

09 NOV 2020 12:00

PC Close Date & Time

10 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☒

PC Time Stamp

11 NOV 2020 08:43

PC Open Date & Time

10 NOV 2020 12:00

PC Close Date & Time

11 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☒

PC Time Stamp

11 NOV 2020 21:03

PC Open Date & Time

11 NOV 2020 12:00

PC Close Date & Time

12 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

12 NOV 2020 21:53

PC Open Date & Time

12 NOV 2020 12:00

PC Close Date & Time

13 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

13 NOV 2020 21:52

PC Open Date & Time

13 NOV 2020 12:00

PC Close Date & Time

14 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

15 NOV 2020 07:15

PC Open Date & Time

14 NOV 2020 12:00

PC Close Date & Time

15 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time Stamp

PC Open Date & Time

15 NOV 2020 12:00

PC Close Date & Time

16 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☒

PC Time Stamp

16 NOV 2020 12:09

PC Open Date & Time

16 NOV 2020 12:00

PC Close Date & Time

17 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 16

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time Stamp

PC Open Date & Time

17 NOV 2020 12:00

PC Close Date & Time

18 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 17

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time Stamp

PC Open Date & Time

18 NOV 2020 12:00

PC Close Date & Time

19 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 10 NOV 2020 06:35

PC Open Date & Time 09 NOV 2020 12:00

PC Close Date & Time 10 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 11 NOV 2020 08:43

PC Open Date & Time 10 NOV 2020 12:00

PC Close Date & Time 11 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp

11 NOV 2020 21:04

PC Open Date & Time

11 NOV 2020 12:00

PC Close Date & Time

12 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 12 NOV 2020 21:53

PC Open Date & Time 12 NOV 2020 12:00

PC Close Date & Time 13 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 13 NOV 2020 21:52

PC Open Date & Time 13 NOV 2020 12:00

PC Close Date & Time 14 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 15 NOV 2020 07:16

PC Open Date & Time 14 NOV 2020 12:00

PC Close Date & Time 15 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

15 NOV 2020 12:00

PC Close Date & Time

16 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 16 NOV 2020 12:09

PC Open Date & Time 16 NOV 2020 12:00

PC Close Date & Time 17 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 16

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

17 NOV 2020 12:00

PC Close Date & Time

18 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 17

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

18 NOV 2020 12:00

PC Close Date & Time

19 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:38:11

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 10 NOV 2020 06:35

PC Open Date & Time 09 NOV 2020 12:00

PC Close Date & Time 10 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 9

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 11 NOV 2020 08:43

PC Open Date & Time 10 NOV 2020 12:00

PC Close Date & Time 11 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 10

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 11 NOV 2020 21:04

PC Open Date & Time 11 NOV 2020 12:00

PC Close Date & Time 12 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 11

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 12 NOV 2020 21:53

PC Open Date & Time 12 NOV 2020 12:00

PC Close Date & Time 13 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 12

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 NOV 2020 21:53

PC Open Date & Time 13 NOV 2020 12:00

PC Close Date & Time 14 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 13

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 15 NOV 2020 07:16

PC Open Date & Time 14 NOV 2020 12:00

PC Close Date & Time 15 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 14

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

PC Open Date & Time

15 NOV 2020 12:00

PC Close Date & Time

16 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 15

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 16 NOV 2020 12:09

PC Open Date & Time 16 NOV 2020 12:00

PC Close Date & Time 17 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 16

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

PC Open Date & Time

17 NOV 2020 12:00

PC Close Date & Time

18 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 17

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

PC Open Date & Time

18 NOV 2020 12:00

PC Close Date & Time

19 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| 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 | 10 NOV 2020 06:35 |
| PC Open Date & Time | 09 NOV 2020 12:00 |
| PC Close Date & Time | 10 NOV 2020 11:59 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| TIMEPOINT | DAY 9 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input type="checkbox"/> Yes <input checked="" type="checkbox"/> |
| PC Time stamp | 11 NOV 2020 08:43 |
| PC Open Date & Time | 10 NOV 2020 12:00 |
| PC Close Date & Time | 11 NOV 2020 11:59 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| TIMEPOINT | DAY 10 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| PC Time stamp | 11 NOV 2020 21:04 |
| PC Open Date & Time | 11 NOV 2020 12:00 |
| PC Close Date & Time | 12 NOV 2020 11:59 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| TIMEPOINT | DAY 11 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 12 NOV 2020 21:54 |
| PC Open Date & Time | 12 NOV 2020 12:00 |
| PC Close Date & Time | 13 NOV 2020 11:59 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 15:38:11

| | |
|---|------------------------------|
| TIMEPOINT | DAY 12 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input type="checkbox"/> |
| | Yes <input type="checkbox"/> |
| PC Time stamp | |
| PC Open Date & Time | 13 NOV 2020 12:00 |
| PC Close Date & Time | 14 NOV 2020 11:59 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 13

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

No ☐

Yes ☒

PC Time stamp

15 NOV 2020 07:16

PC Open Date & Time

14 NOV 2020 12:00

PC Close Date & Time

15 NOV 2020 11:59

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 15:38:11

| | |
|---|------------------------------|
| TIMEPOINT | DAY 14 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input type="checkbox"/> |
| | Yes <input type="checkbox"/> |
| PC Time stamp | |
| PC Open Date & Time | 15 NOV 2020 12:00 |
| PC Close Date & Time | 16 NOV 2020 11:59 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| TIMEPOINT | DAY 15 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| PC Time stamp | 16 NOV 2020 12:09 |
| PC Open Date & Time | 16 NOV 2020 12:00 |
| PC Close Date & Time | 17 NOV 2020 11:59 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 15:38:11

| | |
|---|------------------------------|
| TIMEPOINT | DAY 16 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input type="checkbox"/> |
| | Yes <input type="checkbox"/> |
| PC Time stamp | |
| PC Open Date & Time | 17 NOV 2020 12:00 |
| PC Close Date & Time | 18 NOV 2020 11:59 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 15:38:11

| | |
|---|------------------------------|
| TIMEPOINT | DAY 17 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input type="checkbox"/> |
| | Yes <input type="checkbox"/> |
| PC Time stamp | |
| PC Open Date & Time | 18 NOV 2020 12:00 |
| PC Close Date & Time | 19 NOV 2020 11:59 |

US3192734

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 25 Apr 2021 17:54:10

Generated On: 09 Jun 2021 15:38:11

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 10 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3192734

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 03:28:21

Generated On: 09 Jun 2021 15:38:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192734

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 03:28:21

Generated On: 09 Jun 2021 15:38:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192734

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 03:28:21

Generated On: 09 Jun 2021 15:38:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192734

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 03:28:21

Generated On: 09 Jun 2021 15:38:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192734

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 03:28:21

Generated On: 09 Jun 2021 15:38:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192734

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 03:28:23

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 14 Feb 2021 03:28:23

Generated On: 09 Jun 2021 15:38:11

| | |
|---|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 2 DEC 2020 |
| Time of assessment (<i>00:00-23:59</i>) | 11:30 (24 HR) |
| Vital Signs Date and Time (derived) | 2 DEC 2020 11:30 |
| Temperature (<i>xxx.x</i>) | 97.6 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (<i>xxx</i>) | 89 beats/min |
| Pulse units | BPM |
| Respiratory Rate (<i>xxx</i>) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (<i>xxx</i>) | 89 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (<i>xxx</i>) | 72 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3192734

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 14 Feb 2021 03:28:23

Generated On: 09 Jun 2021 15:38:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 DEC 2020

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

US3192734

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Feb 2021 03:28:23

Generated On: 09 Jun 2021 15:38:11

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 2 DEC 2020 |
| Collection time (00:00-23:59) | 11:40 (24 HR) |
| Collection date and time (derived) | 2 DEC 2020 11:40 |

US3192734

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 03:28:23

Generated On: 09 Jun 2021 15:38:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

| TIMEPOINT | DAY 61 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 03 DEC 2020 11:55:06 |
| Patient Cloud Open Date & Time | 01 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 05 DEC 2020 23:59 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

| TIMEPOINT | DAY 68 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2020 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

| TIMEPOINT | DAY 75 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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 | 17 DEC 2020 12:00:32 |
| Patient Cloud Open Date & Time | 15 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 19 DEC 2020 23:59 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 82

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 DEC 2020 12:00:03

Patient Cloud Open Date & Time

22 DEC 2020 00:01

Patient Cloud Close Date & Time

26 DEC 2020 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

| TIMEPOINT | DAY 89 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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 | 29 DEC 2020 08:25:37 |
| Patient Cloud Open Date & Time | 29 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 02 JAN 2021 23:59 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

| TIMEPOINT | DAY 96 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 05 JAN 2021 08:10:57 |
| Patient Cloud Open Date & Time | 05 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 09 JAN 2021 23:59 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 JAN 2021 12:00:57

Patient Cloud Open Date & Time

12 JAN 2021 00:01

Patient Cloud Close Date & Time

16 JAN 2021 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 JAN 2021 12:06:20

Patient Cloud Open Date & Time

19 JAN 2021 00:01

Patient Cloud Close Date & Time

23 JAN 2021 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 JAN 2021 08:56:22

Patient Cloud Open Date & Time

26 JAN 2021 00:01

Patient Cloud Close Date & Time

30 JAN 2021 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

| 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 | 02 FEB 2021 07:27:15 |
| Patient Cloud Open Date & Time | 02 FEB 2021 00:01 |
| Patient Cloud Close Date & Time | 06 FEB 2021 23:59 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

09 FEB 2021 08:32:29

Patient Cloud Open Date & Time

09 FEB 2021 00:01

Patient Cloud Close Date & Time

13 FEB 2021 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

16 FEB 2021 21:27:39

Patient Cloud Open Date & Time

16 FEB 2021 00:01

Patient Cloud Close Date & Time

20 FEB 2021 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

| TIMEPOINT | DAY 145 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 FEB 2021 00:01 |
| Patient Cloud Close Date & Time | 27 FEB 2021 23:59 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAR 2021 07:33:54

Patient Cloud Open Date & Time

02 MAR 2021 00:01

Patient Cloud Close Date & Time

06 MAR 2021 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

09 MAR 2021 07:16:30

Patient Cloud Open Date & Time

09 MAR 2021 00:01

Patient Cloud Close Date & Time

13 MAR 2021 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 MAR 2021 08:47:15

Patient Cloud Open Date & Time

16 MAR 2021 00:01

Patient Cloud Close Date & Time

20 MAR 2021 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

23 MAR 2021 07:46:53

Patient Cloud Open Date & Time

23 MAR 2021 00:01

Patient Cloud Close Date & Time

27 MAR 2021 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 APR 2021 08:08:28

Patient Cloud Open Date & Time

30 MAR 2021 00:01

Patient Cloud Close Date & Time

03 APR 2021 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 APR 2021 08:32:29

Patient Cloud Open Date & Time

06 APR 2021 00:01

Patient Cloud Close Date & Time

10 APR 2021 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 APR 2021 07:34:57

Patient Cloud Open Date & Time

13 APR 2021 00:01

Patient Cloud Close Date & Time

17 APR 2021 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 APR 2021 11:59:11

Patient Cloud Open Date & Time

20 APR 2021 00:01

Patient Cloud Close Date & Time

24 APR 2021 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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 APR 2021 07:08:45

Patient Cloud Open Date & Time

27 APR 2021 00:01

Patient Cloud Close Date & Time

01 MAY 2021 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

| TIMEPOINT | DAY 215 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

[Patient Cloud Close Date & Time](#)

08 MAY 2021 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2021 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 229

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

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

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

[Patient Cloud Close Date & Time](#)

22 MAY 2021 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

| TIMEPOINT | DAY 236 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

[Patient Cloud Close Date & Time](#)

29 MAY 2021 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 JUN 2021 00:01 |
| Patient Cloud Close Date & Time | 05 JUN 2021 23:59 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

[Patient Cloud Close Date & Time](#)

12 JUN 2021 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

[Patient Cloud Close Date & Time](#)

19 JUN 2021 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

22 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2021 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

[Patient Cloud Close Date & Time](#)

03 JUL 2021 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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 ☐

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 JUL 2021 00:01 |
| Patient Cloud Close Date & Time | 10 JUL 2021 23:59 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 JUL 2021 00:01 |
| Patient Cloud Close Date & Time | 17 JUL 2021 23:59 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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 ☐
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 ☐

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2021 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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 ☐

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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 ☐

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

[Patient Cloud Close Date & Time](#)

28 AUG 2021 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2021 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 SEP 2021 00:01 |
| Patient Cloud Close Date & Time | 11 SEP 2021 23:59 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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 ☐ 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 ☐

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 SEP 2021 00:01 |
| Patient Cloud Close Date & Time | 18 SEP 2021 23:59 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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 ☐

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 SEP 2021 00:01 |
| Patient Cloud Close Date & Time | 25 SEP 2021 23:59 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 362

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

[Patient Cloud Close Date & Time](#)

02 OCT 2021 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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 ☐

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 OCT 2021 00:01 |
| Patient Cloud Close Date & Time | 09 OCT 2021 23:59 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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 ☐

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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°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 ☐

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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 ☐

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 OCT 2021 00:01 |
| Patient Cloud Close Date & Time | 30 OCT 2021 23:59 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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 ☐

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

06 NOV 2021 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

[Patient Cloud Close Date & Time](#)

13 NOV 2021 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

| TIMEPOINT | DAY 411 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

20 NOV 2021 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

[Patient Cloud Close Date & Time](#)

27 NOV 2021 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

[Patient Cloud Close Date & Time](#)

04 DEC 2021 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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°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 ☐

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

11 DEC 2021 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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 ☐

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 18 DEC 2021 23:59 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 25 DEC 2021 23:59 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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 ☐

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

[Patient Cloud Close Date & Time](#)

01 JAN 2022 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

| TIMEPOINT | DAY 460 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

[Patient Cloud Close Date & Time](#)

08 JAN 2022 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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 ☐

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

[Patient Cloud Close Date & Time](#)

15 JAN 2022 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

[Patient Cloud Close Date & Time](#)

22 JAN 2022 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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 ☐ 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 ☐

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

| | |
|---|-------------------|
| Patient Cloud Close Date & Time | 29 JAN 2022 23:59 |
|---|-------------------|

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

[Patient Cloud Close Date & Time](#)

05 FEB 2022 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

[Patient Cloud Close Date & Time](#)

12 FEB 2022 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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 ☐

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 FEB 2022 00:01 |
| Patient Cloud Close Date & Time | 19 FEB 2022 23:59 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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 ☐

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

[Patient Cloud Close Date & Time](#)

26 FEB 2022 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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 ☐

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

[Patient Cloud Close Date & Time](#)

05 MAR 2022 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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 ☐

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

[Patient Cloud Close Date & Time](#)

12 MAR 2022 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 MAR 2022 00:01 |
| Patient Cloud Close Date & Time | 19 MAR 2022 23:59 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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 ☐

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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 ☐

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

[Patient Cloud Close Date & Time](#)

02 APR 2022 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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 ☐

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 APR 2022 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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 ☐

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 APR 2022 00:01 |
| Patient Cloud Close Date & Time | 16 APR 2022 23:59 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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 ☐

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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 ☐

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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°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 ☐

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

[Patient Cloud Close Date & Time](#)

07 MAY 2022 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

[Patient Cloud Close Date & Time](#)

14 MAY 2022 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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 ☐

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

[Patient Cloud Close Date & Time](#)

21 MAY 2022 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

| 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"/> |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

| 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"/> |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUN 2022 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

| TIMEPOINT | DAY 614 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

[Patient Cloud Close Date & Time](#)

11 JUN 2022 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

[Patient Cloud Close Date & Time](#)

18 JUN 2022 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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 ☐

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUN 2022 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

| TIMEPOINT | DAY 635 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

[Patient Cloud Close Date & Time](#)

02 JUL 2022 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUL 2022 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 649

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

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

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

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

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

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

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

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 JUL 2022 00:01 |
| Patient Cloud Close Date & Time | 16 JUL 2022 23:59 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

[Patient Cloud Close Date & Time](#)

06 AUG 2022 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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°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 ☐

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

[Patient Cloud Close Date & Time](#)

13 AUG 2022 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

| 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"/> |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

| 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"/> |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

[Patient Cloud Close Date & Time](#)

27 AUG 2022 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

03 SEP 2022 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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 ☐

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

[Patient Cloud Close Date & Time](#)

10 SEP 2022 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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°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 ☐

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 SEP 2022 00:01 |
| Patient Cloud Close Date & Time | 17 SEP 2022 23:59 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 SEP 2022 00:01 |
| Patient Cloud Close Date & Time | 24 SEP 2022 23:59 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

[Patient Cloud Close Date & Time](#)

01 OCT 2022 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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 ☐

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 OCT 2022 00:01 |
| Patient Cloud Close Date & Time | 08 OCT 2022 23:59 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 OCT 2022 00:01 |
| Patient Cloud Close Date & Time | 15 OCT 2022 23:59 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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 ☐

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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 ☐

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

29 OCT 2022 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 761

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

[Patient Cloud Close Date & Time](#)

05 NOV 2022 23:59

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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 ☐

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 NOV 2022 00:01 |
| Patient Cloud Close Date & Time | 12 NOV 2022 23:59 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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°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 ☐

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 NOV 2022 00:01 |
| Patient Cloud Close Date & Time | 19 NOV 2022 23:59 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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 ☐

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 NOV 2022 00:01 |
| Patient Cloud Close Date & Time | 03 DEC 2022 23:59 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 DEC 2022 00:01 |
| Patient Cloud Close Date & Time | 10 DEC 2022 23:59 |

US3192734

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:38:11

| 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 | | 01 MAR 2021 09:43:23 |

US3192734

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 17:36:24

Generated On: 09 Jun 2021 15:38:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192734

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 17:36:24

Generated On: 09 Jun 2021 15:38:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192734

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 14:32:43

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 14:32:43

Generated On: 09 Jun 2021 15:38:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192734

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 14:32:43

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 14:32:43

Generated On: 09 Jun 2021 15:38:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192734

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 01:46:37

Generated On: 09 Jun 2021 15:38:11

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 1 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3192734

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 01:46:37

Generated On: 09 Jun 2021 15:38:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192734

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 19 Apr 2021 20:01:44

Generated On: 09 Jun 2021 15:38:11

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 19 APR 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 |
|------------|--------|

US3192734

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Apr 2021 20:01:44

Generated On: 09 Jun 2021 15:38:11

| | |
|---|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 19 APR 2021 |
| Time of assessment (<i>00:00-23:59</i>) | 09:25 (24 HR) |
| Vital Signs Date and Time (derived) | 19 APR 2021 09:25 |
| Temperature (<i>xxx.x</i>) | 97.6 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (<i>xxx</i>) | 78 beats/min |
| Pulse units | BPM |
| Respiratory Rate (<i>xxx</i>) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (<i>xxx</i>) | 119 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (<i>xxx</i>) | 81 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3192734

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Apr 2021 20:01:44

Generated On: 09 Jun 2021 15:38:11

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.

US3192734

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Apr 2021 20:01:44

Generated On: 09 Jun 2021 15:38:11

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

| | |
|-------------------------------|-------------|
| Collection date (dd MMM yyyy) | 19 APR 2021 |
|-------------------------------|-------------|

| | |
|-------------------------------|---------------|
| Collection time (00:00-23:59) | 09:44 (24 HR) |
|-------------------------------|---------------|

| | |
|------------------------------------|-------------------|
| Collection date and time (derived) | 19 APR 2021 09:44 |
|------------------------------------|-------------------|

US3192734

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 19 Apr 2021 20:01:44

Generated On: 09 Jun 2021 15:38:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192734

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:11

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 08 Apr 2021 01:46:36

Generated On: 09 Jun 2021 15:38:11

Date of Contact 10 NOV 2020

Time of Contact

Date and Time of Contact (derived)

Type of Contact

Clinic Visit - Scheduled ☐

Clinical Visit - Unscheduled ☐

Safety Call ☒

Convalescent Tele-visit ☐

Has the subject reported symptoms of SARS-COV-2?

Yes ☒

No ☐

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 08 Apr 2021 01:46:36

Generated On: 09 Jun 2021 15:38:11

Symptom Day

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

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 08 Apr 2021 01:46:36

Generated On: 09 Jun 2021 15:38:11

| | | |
|--|--------|--------------------------|
| | 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 | 05 NOV 2020 |
|------|-------------|

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

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

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

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

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

390 of 3379

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 08 Apr 2021 01:46:36

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 08 Apr 2021 01:46:36

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 08 Apr 2021 01:46:36

Generated On: 09 Jun 2021 15:38:11

Symptom Day

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

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 08 Apr 2021 01:46:36

Generated On: 09 Jun 2021 15:38:11

| | | |
|--|--------|--------------------------|
| | 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 | 06 NOV 2020 |
|------|-------------|

| | |
|---------------------|------|
| Assessment Not Done | True |
|---------------------|------|

| | |
|---------------|----------------------|
| O2 Saturation | <input type="text"/> |
|---------------|----------------------|

| | |
|---------------------|----------------------|
| O2 Saturation Units | <input type="text"/> |
|---------------------|----------------------|

| | |
|-------------|----------------------|
| Temperature | <input type="text"/> |
|-------------|----------------------|

| | | |
|--------|----------|--------------------------|
| 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)

394 of 3379

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 08 Apr 2021 01:46:36

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 08 Apr 2021 01:46:36

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 08 Apr 2021 01:46:36

Generated On: 09 Jun 2021 15:38:11

Symptom Day

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

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 08 Apr 2021 01:46:36

Generated On: 09 Jun 2021 15:38:11

| | | |
|--|--------|--------------------------|
| | 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 | 07 NOV 2020 |
|------|-------------|

| | |
|---------------------|------|
| Assessment Not Done | True |
|---------------------|------|

| | |
|---------------|--|
| 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)

398 of 3379

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 08 Apr 2021 01:46:36

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 08 Apr 2021 01:46:36

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 08 Apr 2021 01:46:36

Generated On: 09 Jun 2021 15:38:11

Symptom Day

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

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 08 Apr 2021 01:46:36

Generated On: 09 Jun 2021 15:38:11

| | | |
|----------------------|----------------------|--------------------------|
| | 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 | 08 NOV 2020 | |
| Assessment Not Done | True | |
| O2 Saturation | <input type="text"/> | |
| O2 Saturation Units | <input type="text"/> | |
| Temperature | <input type="text"/> | |
| 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)

402 of 3379

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 08 Apr 2021 01:46:36

Generated On: 09 Jun 2021 15:38:11

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

403 of 3379

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 08 Apr 2021 01:46:36

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 08 Apr 2021 01:46:36

Generated On: 09 Jun 2021 15:38:11

Symptom Day

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

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 08 Apr 2021 01:46:36

Generated On: 09 Jun 2021 15:38:11

| | | |
|----------------------|----------------------|--------------------------|
| | 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 | 09 NOV 2020 | |
| Assessment Not Done | True | |
| O2 Saturation | <input type="text"/> | |
| O2 Saturation Units | <input type="text"/> | |
| Temperature | <input type="text"/> | |
| 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)

406 of 3379

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 08 Apr 2021 01:46:36

Generated On: 09 Jun 2021 15:38:11

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

407 of 3379

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 08 Apr 2021 01:46:36

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 08 Apr 2021 01:46:36

Generated On: 09 Jun 2021 15:38:11

Symptom Day

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

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 08 Apr 2021 01:46:36

Generated On: 09 Jun 2021 15:38:11

| | | |
|----------------------|-------------|-------------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 10 NOV 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 95 % | |
| O2 Saturation Units | % | |
| Temperature | 99.2 F | |
| Chills | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input checked="" type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Cough | None | <input type="checkbox"/> |
| | Mild | <input checked="" 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 checked="" type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Difficulty Breathing | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input checked="" type="checkbox"/> |
| | Severe | <input type="checkbox"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

410 of 3379

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 08 Apr 2021 01:46:36

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 08 Apr 2021 01:46:36

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 08 Apr 2021 01:46:36

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| Date of Visit | 10 NOV 2020 |
| Was the Subject Tested For SARS-CoV-2 by RT-PCR? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Did Subject Test Positive For SARS-CoV-2 by RT-PCR? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Date of Test | 10 NOV 2020 |
| Type of Test Performed | Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/> |
| Other, specify | |
| Was this diagnostic test performed at a lab other than the Study Central Lab? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If yes, provide lab information below | |
| Lab/ Institution Test Performed | |
| CLIA Certified? | Yes <input type="radio"/> No <input type="radio"/> |
| COVID-19 Positive (CSA Programming Field Only) | 0 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 08 Apr 2021 01:46:36

Generated On: 09 Jun 2021 15:38:11

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3192734

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 03 Apr 2021 14:32:43

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 01:46:37

Generated On: 09 Jun 2021 15:38:11

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 10 NOV 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | SICKD1 |

US3192734

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 03 Apr 2021 14:32:43

Generated On: 09 Jun 2021 15:38:11

| | |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 10 NOV 2020 |
| Time of assessment (00:00-23:59) | 13:43 (24 HR) |
| Vital Signs Date and Time (derived) | 10 NOV 2020 13:43 |
| Height (xxx.x) | ND - Not Done |
| Weight (xxx.x) | ND - Not Done |
| Temperature (xxx.x) | 99.2 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 97 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 20 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 120 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 80 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3192734

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 14:32:43

Generated On: 09 Jun 2021 15:38:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 NOV 2020

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

US3192734

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 03 Apr 2021 14:32:43

Generated On: 09 Jun 2021 15:38:11

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

10 NOV 2020

US3192734

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 14:32:43

Generated On: 09 Jun 2021 15:38:11

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID SICKD28

US3192734

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 03 Apr 2021 14:32:43

Generated On: 09 Jun 2021 15:38:11

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) _____

US3192734

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 14:32:43

Generated On: 09 Jun 2021 15:38:11

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.

US3192734

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 03 Apr 2021 14:32:43

Generated On: 09 Jun 2021 15:38:11

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☒

Date of Collection

US3192734

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

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 14:32:43

Generated On: 09 Jun 2021 15:38:11

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 30 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 |

US3192734

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

Form: Unblinding

Data signed: (b) (4) 12 Apr 2021 18:02:51

Generated On: 09 Jun 2021 15:38:11

| | |
|---|---|
| Date of updated informed consent (<i>dd MMM yyyy</i>) | 30 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>) | 30 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 |

US3192734

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 03 Apr 2021 14:32:43

Generated On: 09 Jun 2021 15:38:11

| | |
|-------------|---------------|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| BMI (xxx.x) | |

US3192734

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 03 Apr 2021 14:32:43

Generated On: 09 Jun 2021 15:38:11

| | |
|-------------------------------------|--|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| BMI (xxx.x) | |
| Timepoint | Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 30 JAN 2021 |
| Time of assessment (00:00-23:59) | 13:48 (24 HR) |
| Vital Signs Date and Time (derived) | 30 JAN 2021 13:48 |
| Temperature (xxx.x) | 96.5 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 66 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 132 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 85 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3192734

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 03 Apr 2021 14:32:43

Generated On: 09 Jun 2021 15:38:11

| | |
|-------------------------------------|--|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| BMI (xxx.x) | |
| Timepoint | Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 30 JAN 2021 |
| Time of assessment (00:00-23:59) | 15:08 (24 HR) |
| Vital Signs Date and Time (derived) | 30 JAN 2021 15:08 |
| Temperature (xxx.x) | 97.6 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 72 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 126 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 87 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3192734

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

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 14:32:43

Generated On: 09 Jun 2021 15:38:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 JAN 2021

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

US3192734

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

Form: Exposure

Data signed: (b) (4) 03 Apr 2021 14:32:43

Generated On: 09 Jun 2021 15:38:11

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) 30 JAN 2021

What was the treatment time? (00:00-23:59) 14:38 (24 HR)

Treatment Date and Time (derived) 30 JAN 2021 14:38

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

US3192734

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Apr 2021 14:32:43

Generated On: 09 Jun 2021 15:38:11

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

| | |
|-------------------------------|-------------|
| Collection date (dd MMM yyyy) | 30 JAN 2021 |
|-------------------------------|-------------|

| | |
|-------------------------------|---------------|
| Collection time (00:00-23:59) | 14:00 (24 HR) |
|-------------------------------|---------------|

| | |
|------------------------------------|-------------------|
| Collection date and time (derived) | 30 JAN 2021 14:00 |
|------------------------------------|-------------------|

US3192734

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 03 Apr 2021 14:32:43

Generated On: 09 Jun 2021 15:38:11

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 30 JAN 2021 |
| Collection time (00:00 - 23:59) | 14:05 |
| Collection Date and Time (derived) | 30 JAN 2021 14:05 |

US3192734

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

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 14:32:43

Generated On: 09 Jun 2021 15:38:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192734

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 14:32:43

Generated On: 09 Jun 2021 15:38:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192734

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 14:32:43

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 14:32:43

Generated On: 09 Jun 2021 15:38:11

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 1 MAR 2021 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | OLD29 |

US3192734

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 03 Apr 2021 14:32:43

Generated On: 09 Jun 2021 15:38:11

| | |
|-------------------------------------|---|
| Timepoint | Pre-Dose <input checked="" type="radio"/> |
| | Post-Dose <input type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 1 MAR 2021 |
| Time of assessment (00:00-23:59) | 14:20 (24 HR) |
| Vital Signs Date and Time (derived) | 1 MAR 2021 14:20 |
| Temperature (xxx.x) | 97.9 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 80 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 12 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 112 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 75 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3192734

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 03 Apr 2021 14:32:43

Generated On: 09 Jun 2021 15:38:11

| | |
|-------------------------------------|--|
| Timepoint | Pre-Dose <input type="radio"/> |
| | Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 1 MAR 2021 |
| Time of assessment (00:00-23:59) | 15:08 (24 HR) |
| Vital Signs Date and Time (derived) | 1 MAR 2021 15:08 |
| Temperature (xxx.x) | 98.1 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 84 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 113 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 82 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3192734

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 14:32:43

Generated On: 09 Jun 2021 15:38:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 MAR 2021

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

US3192734

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 03 Apr 2021 14:32:43

Generated On: 09 Jun 2021 15:38:11

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) 1 MAR 2021

What was the treatment time? (00:00-23:59) 14:38 (24 HR)

Treatment Date and Time (derived) 1 MAR 2021 14:38

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

US3192734

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 14:32:43

Generated On: 09 Jun 2021 15:38:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192734

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 14:32:43

Generated On: 09 Jun 2021 15:38:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192734

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 14:32:43

Generated On: 09 Jun 2021 15:38:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192734

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 14:32:43

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 03 Apr 2021 14:32:43

Generated On: 09 Jun 2021 15:38:11

| | |
|---|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 2 APR 2021 |
| Time of assessment (<i>00:00-23:59</i>) | 08:36 (24 HR) |
| Vital Signs Date and Time (derived) | 2 APR 2021 08:36 |
| Temperature (<i>xxx.x</i>) | 97.2 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (<i>xxx</i>) | 61 beats/min |
| Pulse units | BPM |
| Respiratory Rate (<i>xxx</i>) | 12 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (<i>xxx</i>) | 144 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (<i>xxx</i>) | 91 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3192734

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 14:32:43

Generated On: 09 Jun 2021 15:38:11

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.

US3192734

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Apr 2021 14:32:43

Generated On: 09 Jun 2021 15:38:11

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 2 APR 2021 |
| Collection time (00:00-23:59) | 08:47 (24 HR) |
| Collection date and time (derived) | 2 APR 2021 08:47 |

US3192734

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 28 Mar 2021 18:41:43

Generated On: 09 Jun 2021 15:38:11

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3192734

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Apr 2021 12:37:11

Generated On: 09 Jun 2021 15:38:11

| | |
|--|--|
| AEID | USA-US097-2021-MRNA-1273-P30 1000006 |
| Adverse event | RLL PNEUMONIA |
| 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) | 18 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) | 25 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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | True |
| Hospital Admission Date (dd MMM yyyy) | 18 NOV 2020 |
| Hospital Discharge Date (dd MMM yyyy) | 25 NOV 2020 |
| Admitted to ICU? | Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/> |

PRODUCTION RELEASE (v12.003
EAB) (1725)

449 of 3379

US3192734

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Apr 2021 12:37:11

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Apr 2021 12:37:11

Generated On: 09 Jun 2021 15:38:11

PER PI NOTE, ON 11/18/2020, HUSBAND REPORTED PATIENT LOOKED DAZED, CALLED 911 AND WAS ADMITTED. PATIENT RECEIVED IV ABX (VANCOMYCIN, METRONIDAZOLE, CEPHALOSPORIN) AND OXYGEN. PATIENT WAS DISCHARGED FROM HOSPITAL ON 11/25/2020 WITH OXYGEN AND DIAGNOSED WITH VALLEY FEVER AND SCAR TISSUE FROM PREVIOUS RADIATION. PATIENT HAS CHRONIC PULMONARY FIBROSIS DUE TO RADIATION TREATMENT FOR HISTORY OF HODGKIN'S LYMPHOMA IN 1999. PER PI, THIS SAE IS NOT RELATED TO INVESTIGATIONAL VACCINE.

| | |
|--|---|
| 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 |

US3192734

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Apr 2021 12:37:11

Generated On: 09 Jun 2021 15:38:11

| | |
|--|--|
| AEID | USA-US097-2021-MRNA-1273-P30 1000006 |
| Adverse event | HYPOXIA DUE TO RLL PNEUMONIA |
| 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) | 18 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) | 25 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) | 18 NOV 2020 |
| Hospital Discharge Date (dd MMM yyyy) | 25 NOV 2020 |
| Admitted to ICU? | Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/> |
| PRODUCTION RELEASE (v12.003 EAB) (1725) | 452 of 3379 |

US3192734

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Apr 2021 12:37:11

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Apr 2021 12:37:11

Generated On: 09 Jun 2021 15:38:11

PER PI NOTE, ON 11/18/2020, HUSBAND REPORTED PATIENT LOOKED DAZED, CALLED 911 AND WAS ADMITTED. PATIENT RECEIVED IV ABX (VANCOMYCIN, METRONIDAZOLE, CEPHALOSPORIN) AND OXYGEN. PATIENT WAS DISCHARGED FROM HOSPITAL ON 11/25/2020 WITH OXYGEN AND DIAGNOSED WITH VALLEY FEVER AND SCAR TISSUE FROM PREVIOUS RADIATION. PATIENT HAS CHRONIC PULMONARY FIBROSIS DUE TO RADIATION TREATMENT FOR HISTORY OF HODGKIN'S LYMPHOMA IN 1999. PER PI, THIS SAE IS NOT RELATED TO INVESTIGATIONAL VACCINE.

| | |
|--|---|
| 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 |

US3192734

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 08 Apr 2021 12:37:11

Generated On: 09 Jun 2021 15:38:11

| | |
|--|--|
| AEID | USA-US097-2021-MRNA-1273-P30 1000006 |
| Adverse event | VALLEY FEVER |
| 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) | 21 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) | 02 DEC 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) | 18 NOV 2020 |
| Hospital Discharge Date (dd MMM yyyy) | 25 NOV 2020 |
| Admitted to ICU? | Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/> |

PRODUCTION RELEASE (v12.003
EAB) (1725)

455 of 3379

US3192734

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 08 Apr 2021 12:37:11

Generated On: 09 Jun 2021 15:38:11

| | |
|--|---|
| 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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/> |
| Other action taken (check all that apply) | |
| None | False |
| Concomitant Medication | True |
| Concomitant Procedure | False |
| Outcome | Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | |

US3192734

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 08 Apr 2021 12:37:11

Generated On: 09 Jun 2021 15:38:11

PER PI NOTE, ON 11/18/2020, HUSBAND REPORTED PATIENT LOOKED DAZED, CALLED 911 AND WAS ADMITTED. PATIENT RECEIVED IV ABX (VANCOMYCIN, METRONIDAZOLE, CEPHALOSPORIN) AND OXYGEN. PATIENT WAS DISCHARGED FROM HOSPITAL ON 11/25/2020 WITH OXYGEN AND DIAGNOSED WITH VALLEY FEVER AND SCAR TISSUE FROM PREVIOUS RADIATION. PATIENT HAS CHRONIC PULMONARY FIBROSIS DUE TO RADIATION TREATMENT FOR HISTORY OF HODGKIN'S LYMPHOMA IN 1999. PER PI, THIS SAE IS NOT RELATED TO INVESTIGATIONAL VACCINE.

| | |
|--|---|
| 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 |

US3192734

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 08 Apr 2021 12:37:11

Generated On: 09 Jun 2021 15:38:11

| | |
|--|--|
| AEID | |
| Adverse event | CHILLS |
| 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) | 11 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) | 11 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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | False |
| Hospital Admission Date (dd MMM yyyy) | |
| Hospital Discharge Date (dd MMM yyyy) | |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |
| Number of Days in ICU | |

PRODUCTION RELEASE (v12.003
EAB) (1725)

458 of 3379

US3192734

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 08 Apr 2021 12:37:11

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 08 Apr 2021 12:37:11

Generated On: 09 Jun 2021 15:38:11

| | |
|--|--|
| AEID | |
| Adverse event | FATIGUE |
| Was this a medically-attended AE? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Was this a Solicited Adverse Reaction? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Is this event a confirmed diagnosis of Symptomatic Covid-19? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Start date (dd MMM yyyy) | 03 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) | 02 DEC 2020 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | False |
| Hospital Admission Date (dd MMM yyyy) | |
| Hospital Discharge Date (dd MMM yyyy) | |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |
| Number of Days in ICU | |

PRODUCTION RELEASE (v12.003
EAB) (1725)

460 of 3379

US3192734

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 08 Apr 2021 12:37:11

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 08 Apr 2021 12:37:11

Generated On: 09 Jun 2021 15:38:11

AEID

Adverse event

BODY ACHES

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

05 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

18 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

462 of 3379

EAB) (1725)

US3192734

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 08 Apr 2021 12:37:11

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 08 Apr 2021 12:37:11

Generated On: 09 Jun 2021 15:38:11

| | |
|--|--|
| AEID | |
| Adverse event | HEADACHE |
| Was this a medically-attended AE? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Was this a Solicited Adverse Reaction? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Is this event a confirmed diagnosis of Symptomatic Covid-19? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Start date (dd MMM yyyy) | 05 NOV 2020 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | 18 NOV 2020 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | False |
| Hospital Admission Date (dd MMM yyyy) | |
| Hospital Discharge Date (dd MMM yyyy) | |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |
| Number of Days in ICU | |

PRODUCTION RELEASE (v12.003
EAB) (1725)

464 of 3379

US3192734

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 08 Apr 2021 12:37:11

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 08 Apr 2021 12:37:11

Generated On: 09 Jun 2021 15:38:11

| | |
|--|--|
| AEID | USA-US097-2021-MRNA-1273-P30 1000006 |
| Adverse event | WORSENING OF CHRONIC PULMONARY FIBROSIS |
| 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) | 11 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) | 22 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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | True |
| Hospital Admission Date (dd MMM yyyy) | 18 NOV 2020 |
| Hospital Discharge Date (dd MMM yyyy) | 25 NOV 2020 |
| Admitted to ICU? | Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/> |
| PRODUCTION RELEASE (v12.003 EAB) (1725) | 466 of 3379 |

US3192734

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 08 Apr 2021 12:37:11

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 08 Apr 2021 12:37:11

Generated On: 09 Jun 2021 15:38:11

PER PI NOTE, ON 11/18/2020, HUSBAND REPORTED PATIENT LOOKED DAZED, CALLED 911 AND WAS ADMITTED. PATIENT RECEIVED IV ABX (VANCOMYCIN, METRONIDAZOLE, CEPHALOSPORIN) AND OXYGEN. PATIENT WAS DISCHARGED FROM HOSPITAL ON 11/25/2020 WITH OXYGEN AND DIAGNOSED WITH VALLEY FEVER AND SCAR TISSUE FROM PREVIOUS RADIATION. PATIENT HAS CHRONIC PULMONARY FIBROSIS DUE TO RADIATION TREATMENT FOR HISTORY OF HODGKIN'S LYMPHOMA IN 1999. PER PI, THIS SAE IS NOT RELATED TO INVESTIGATIONAL VACCINE.

| | |
|--|---|
| 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 |

US3192734

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 08 Apr 2021 12:37:11

Generated On: 09 Jun 2021 15:38:11

| | |
|--|--|
| AEID | |
| Adverse event | SORE ARM POST INJECTION |
| Was this a medically-attended AE? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Was this a Solicited Adverse Reaction? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Is this event a confirmed diagnosis of Symptomatic Covid-19? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Start date (dd MMM yyyy) | 30 JAN 2021 |
| 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) | 31 JAN 2021 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | False |
| Hospital Admission Date (dd MMM yyyy) | |
| Hospital Discharge Date (dd MMM yyyy) | |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |
| Number of Days in ICU | |

PRODUCTION RELEASE (v12.003
EAB) (1725)

469 of 3379

US3192734

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 08 Apr 2021 12:37:11

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 08 Apr 2021 12:37:11

Generated On: 09 Jun 2021 15:38:11

| | |
|--|--|
| AEID | |
| Adverse event | FATIGUE |
| Was this a medically-attended AE? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Was this a Solicited Adverse Reaction? | Yes <input 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) | 02 MAR 2021 |
| 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) | 03 MAR 2021 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | False |
| Hospital Admission Date (dd MMM yyyy) | |
| Hospital Discharge Date (dd MMM yyyy) | |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |
| Number of Days in ICU | |

US3192734

Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 08 Apr 2021 12:37:11

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 08 Apr 2021 12:37:11

Generated On: 09 Jun 2021 15:38:11

AEID

Adverse event

GENERALIZED JOINT ACHES

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

05 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

16 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

473 of 3379

EAB) (1725)

US3192734

Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 08 Apr 2021 12:37:11

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 03 Apr 2021 14:32:43

Generated On: 09 Jun 2021 15:38:11

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

Yes ☒

No ☐

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

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 12:37:12

Generated On: 09 Jun 2021 15:38:11

Name of Medication PROPRANOLOL

Prophylaxis Yes ☐
No ☒

Indication SINUS TACHYCARDIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

476 of 3379

EAB) (1725)

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 12:37:12

Generated On: 09 Jun 2021 15:38:11

| | | |
|--|--------------------------|----------------------------------|
| | 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 SEP 2019 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 12:37:12

Generated On: 09 Jun 2021 15:38:11

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

478 of 3379

EAB) (1725)

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 12:37:12

Generated On: 09 Jun 2021 15:38:11

| | | |
|--|--------------------------|----------------------------------|
| | 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 SEP 2019 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 12:37:12

Generated On: 09 Jun 2021 15:38:11

Name of Medication ALPRAZOLAM

Prophylaxis Yes ☐
No ☒

Indication ANXIETY/INSOMNIA

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

480 of 3379

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 12:37:12

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 12:37:12

Generated On: 09 Jun 2021 15:38:11

Name of Medication VENLAFAXINE

Prophylaxis Yes ☐
No ☒

Indication ANXIETY/DEPRESSION

Dose per administration 37.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

482 of 3379

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 12:37:12

Generated On: 09 Jun 2021 15:38:11

| | | |
|--|--------------------------|----------------------------------|
| | 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 MAR 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 2 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 12:37:12

Generated On: 09 Jun 2021 15:38:11

Name of Medication MELATONIN

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

484 of 3379

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 12:37:12

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 12:37:12

Generated On: 09 Jun 2021 15:38:11

Name of Medication MULTI VITAMIN

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

486 of 3379

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 12:37:12

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 12:37:12

Generated On: 09 Jun 2021 15:38:11

Name of Medication FISH OIL

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

488 of 3379

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 12:37:12

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 12:37:12

Generated On: 09 Jun 2021 15:38:11

Name of Medication VITAMIN D

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 5000

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)

490 of 3379

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 12:37:12

Generated On: 09 Jun 2021 15:38:11

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

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 12:37:12

Generated On: 09 Jun 2021 15:38:11

| | |
|--------------------|--------------------------------------|
| Name of Medication | FLU SHOT |
| Prophylaxis | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |

| | |
|-------------------------|-------------------------------------|
| Indication | FLU PREVENTION |
| Dose per administration | 0.5 |
| Dose unit | mg <input type="radio"/> |
| | ug <input type="radio"/> |
| | mL <input checked="" type="radio"/> |
| | g <input type="radio"/> |
| | IU <input type="radio"/> |
| | tablet <input type="radio"/> |
| | capsule <input type="radio"/> |
| | puff <input type="radio"/> |
| | Other <input type="radio"/> |

If dose unit is Other, specify

| | |
|-----------|---|
| Frequency | once daily <input type="radio"/> |
| | twice daily <input type="radio"/> |
| | three times daily <input type="radio"/> |
| | four times daily <input type="radio"/> |
| | every other day <input type="radio"/> |
| | every week <input type="radio"/> |
| | every month <input type="radio"/> |
| | as needed <input type="radio"/> |
| | once <input checked="" type="radio"/> |
| | unknown <input type="radio"/> |
| | other <input type="radio"/> |

If frequency is Other, specify

| | |
|-------------------------|------------------------------------|
| Route of administration | Oral <input type="radio"/> |
| | Topical <input type="radio"/> |
| | Subcutaneous <input type="radio"/> |
| | Transdermal <input type="radio"/> |
| | Intraocular <input type="radio"/> |

PRODUCTION RELEASE (v12.003
EAB) (1725)

492 of 3379

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 12:37:12

Generated On: 09 Jun 2021 15:38:11

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input checked="" type="radio"/> |
| | Respiratory (Inhalation) | <input type="radio"/> |
| | Intralesional | <input type="radio"/> |
| | Intraperitoneal | <input type="radio"/> |
| | Nasal | <input type="radio"/> |
| | Vaginal | <input type="radio"/> |
| | Rectal | <input type="radio"/> |
| | Intravenous | <input type="radio"/> |
| | Intravenous Bolus | <input type="radio"/> |
| | Intravenous Drip | <input type="radio"/> |
| | Other | <input type="radio"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | | 18 OCT 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 18 OCT 2020 |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input type="radio"/> |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 12:37:12

Generated On: 09 Jun 2021 15:38:11

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication BODY ACHES FROM INJECTION

Dose per administration 600

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)

494 of 3379

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 12:37:12

Generated On: 09 Jun 2021 15:38:11

| | | |
|--|--------------------------|-------------------------------------|
| | 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) | 5 NOV 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | 18 NOV 2020 | |
| Was this medication taken for solicited event? | Yes | <input checked="" type="checkbox"/> |
| | No | <input type="checkbox"/> |
| Separate Dosage Number (derived) | 2 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input checked="" type="checkbox"/> |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 12:37:12

Generated On: 09 Jun 2021 15:38:11

Name of Medication LEVOFLOXACIN

Prophylaxis Yes ☐
No ☒

Indication RLL PNEUMONIA

Dose per administration 750

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

496 of 3379

EAB) (1725)

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 12:37:12

Generated On: 09 Jun 2021 15:38:11

| | | |
|--|--------------------------|-------------------------------------|
| | 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) | 18 NOV 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 25 NOV 2020 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input checked="" type="checkbox"/> |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 12:37:12

Generated On: 09 Jun 2021 15:38:11

Name of Medication ALBUTEROL INHALER

Prophylaxis Yes ☐
No ☒

Indication RLL PNEUMONIA

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

498 of 3379

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 12:37:12

Generated On: 09 Jun 2021 15:38:11

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="radio"/> |
| | Respiratory (Inhalation) | <input checked="" type="radio"/> |
| | Intralesional | <input type="radio"/> |
| | Intraperitoneal | <input type="radio"/> |
| | Nasal | <input type="radio"/> |
| | Vaginal | <input type="radio"/> |
| | Rectal | <input type="radio"/> |
| | Intravenous | <input type="radio"/> |
| | Intravenous Bolus | <input type="radio"/> |
| | Intravenous Drip | <input type="radio"/> |
| | Other | <input type="radio"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | 18 NOV 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) | 23 NOV 2020 | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | _____ | |
| Interval Dosage Unit Number (derived) | _____ | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input type="radio"/> |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 12:37:12

Generated On: 09 Jun 2021 15:38:11

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication HEADACHE FROM THE
PNEUMONIA

Dose per administration 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)

500 of 3379

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 12:37:12

Generated On: 09 Jun 2021 15:38:11

| | | |
|--|--------------------------|-------------------------------------|
| | 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) | 11 NOV 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | 13 NOV 2020 | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | 2 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input checked="" type="checkbox"/> |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 12:37:12

Generated On: 09 Jun 2021 15:38:11

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 500

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)

502 of 3379

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 12:37:12

Generated On: 09 Jun 2021 15:38:11

| | | |
|--|--------------------------|-------------------------------------|
| | 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) | | 10 NOV 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 16 NOV 2020 |
| Was this medication taken for solicited event? | Yes | <input checked="" type="checkbox"/> |
| | No | <input type="checkbox"/> |
| Separate Dosage Number (derived) | | 2 |
| Interval Dosage Unit Number (derived) | | 1 |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input checked="" type="checkbox"/> |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 08 Apr 2021 12:37:12

Generated On: 09 Jun 2021 15:38:11

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐
No ☒

Indication RLL PNEUMONIA

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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)

504 of 3379

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 08 Apr 2021 12:37:12

Generated On: 09 Jun 2021 15:38:11

| | | |
|--|---|-------------------------------------|
| | 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 checked="" 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) | 18 NOV 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes <input type="checkbox"/> | |
| | No <input checked="" type="checkbox"/> | |
| If not Ongoing, End date (dd MMM yyyy) | 23 NOV 2020 | |
| Was this medication taken for solicited event? | Yes <input type="checkbox"/> | |
| | No <input checked="" type="checkbox"/> | |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 <input type="checkbox"/> | |
| | 803 <input type="checkbox"/> | |
| | 804 <input checked="" type="checkbox"/> | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 08 Apr 2021 12:37:12

Generated On: 09 Jun 2021 15:38:11

Name of Medication METRONIDAZOLE

Prophylaxis Yes ☐
No ☒

Indication RLL PNEUMONIA

Dose per administration UNKNOWN

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

506 of 3379

EAB) (1725)

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 08 Apr 2021 12:37:12

Generated On: 09 Jun 2021 15:38:11

| | | |
|--|--------------------------|-------------------------------------|
| | 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) | 18 NOV 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 23 NOV 2020 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input checked="" type="checkbox"/> |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 08 Apr 2021 12:37:12

Generated On: 09 Jun 2021 15:38:11

Name of Medication CEPHALOSPORIN

Prophylaxis Yes ☐
No ☒

Indication RLL PNEUMONIA

Dose per administration UNKNOWN

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)

508 of 3379

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 08 Apr 2021 12:37:12

Generated On: 09 Jun 2021 15:38:11

| | | |
|--|--------------------------|-------------------------------------|
| | 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 checked="" 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) | 18 NOV 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | 23 NOV 2020 | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input checked="" type="checkbox"/> |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 08 Apr 2021 12:37:12

Generated On: 09 Jun 2021 15:38:11

Name of Medication SUPPLEMENT OXYGEN

Prophylaxis Yes ☐
No ☒

Indication HYPOXIA AND PNEUMONIA

Dose per administration 2-4

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

If dose unit is Other, specify LITERS

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

510 of 3379

EAB) (1725)

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 08 Apr 2021 12:37:12

Generated On: 09 Jun 2021 15:38:11

| | | |
|--|--------------------------|-------------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input checked="" 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) | 18 NOV 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 25 NOV 2020 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input checked="" type="checkbox"/> |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 08 Apr 2021 12:37:12

Generated On: 09 Jun 2021 15:38:11

Name of Medication LEVAQUIN

Prophylaxis Yes ☐
No ☒

Indication RLL PNEUMONIA

Dose per administration 750

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)

512 of 3379

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 08 Apr 2021 12:37:12

Generated On: 09 Jun 2021 15:38:11

| | | |
|--|--------------------------|-------------------------------------|
| | 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) | 18 NOV 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) 18 NOV 2020 | | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input checked="" type="checkbox"/> |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 08 Apr 2021 12:37:12

Generated On: 09 Jun 2021 15:38:11

Name of Medication FLUCONAZOLE

Prophylaxis Yes ☐
No ☒

Indication VALLEY FEVER

Dose per administration 400

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)

514 of 3379

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 08 Apr 2021 12:37:12

Generated On: 09 Jun 2021 15:38:11

| | | |
|--|--------------------------|-------------------------------------|
| | 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) | 21 NOV 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | 05 JAN 2021 | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input checked="" type="checkbox"/> |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 08 Apr 2021 12:37:12

Generated On: 09 Jun 2021 15:38:11

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication SORE ARM POST INJECTION

Dose per administration 400

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)

516 of 3379

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 08 Apr 2021 12:37:12

Generated On: 09 Jun 2021 15:38:11

| | | |
|--|--------------------------|-------------------------------------|
| | 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) | 2 MAR 2021 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 2 MAR 2021 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

US3192734

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 03 Apr 2021 14:32:43

Generated On: 09 Jun 2021 15:38:11

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3192734

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:38:11

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3192734

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:38:11

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 ☐

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 12 Apr 2021 18:02:51

Generated On: 09 Jun 2021 15:38:11

| | |
|--|--|
| SAEID | USA-US097-2021-MRNA-1273-P301000006 |
| 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 checked="" type="radio"/> No <input type="radio"/> |
| Investigator's First Name | JOHN |
| Investigator's Last Name | MCGETTIGAN |
| Site Address: Street | 5390 E. ERICKSON DRIVE |
| Site Address: City | TUCSON |
| Site Address: State | AZ |
| Site Address: Postal Code | 85712 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 5 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 12 Apr 2021 18:02:51

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| SAEID | USA-US097-2021-MRNA-1273-P301000006 |
| 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 checked="" type="radio"/> No <input type="radio"/> |
| Investigator's First Name | JOHN |
| Investigator's Last Name | MCGETTIGAN |
| Site Address: Street | 5390 E. ERICKSON DRIVE |
| Site Address: City | TUCSON |
| Site Address: State | AZ |
| Site Address: Postal Code | 85712 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 5 |
| Date of submission (Pre-filled from custom function) | 25/JAN/2021 12:50 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 12 Apr 2021 18:02:51

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| SAEID | USA-US097-2021-MRNA-1273-P301000006 |
| 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 checked="" type="radio"/> No <input type="radio"/> |
| Investigator's First Name | JOHN |
| Investigator's Last Name | MCGETTIGAN |
| Site Address: Street | 5390 E. ERICKSON DRIVE |
| Site Address: City | TUCSON |
| Site Address: State | AZ |
| Site Address: Postal Code | 85712 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 5 |
| Date of submission (Pre-filled from custom function) | 01/FEB/2021 14:50 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 12 Apr 2021 18:02:51

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| SAEID | USA-US097-2021-MRNA-1273-P301000006 |
| 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 checked="" type="radio"/> No <input type="radio"/> |
| Investigator's First Name | JOHN |
| Investigator's Last Name | MCGETTIGAN |
| Site Address: Street | 5390 E. ERICKSON DRIVE |
| Site Address: City | TUCSON |
| Site Address: State | AZ |
| Site Address: Postal Code | 85712 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 5 |
| Date of submission (Pre-filled from custom function) | 17/MAR/2021 10:58 |
| 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 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Data signed: (b) (4) 12 Apr 2021 18:02:51

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| SAEID | USA-US097-2021-MRNA-1273-P301000006 |
| 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 checked="" type="radio"/> No <input type="radio"/> |
| Investigator's First Name | JOHN |
| Investigator's Last Name | MCGETTIGAN |
| Site Address: Street | 5390 E. ERICKSON DRIVE |
| Site Address: City | TUCSON |
| Site Address: State | AZ |
| Site Address: Postal Code | 85712 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 5 |
| Date of submission (Pre-filled from custom function) | 08/APR/2021 08:06 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form (5)

Data signed: (b) (4) 12 Apr 2021 18:02:51

Generated On: 09 Jun 2021 15:38:11

| | |
|---|--|
| SAEID | USA-US097-2021-MRNA-1273-P301000006 |
| 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 checked="" type="radio"/> No <input type="radio"/> |
| Investigator's First Name | JOHN |
| Investigator's Last Name | MCGETTIGAN |
| Site Address: Street | 5390 E. ERICKSON DRIVE |
| Site Address: City | TUCSON |
| Site Address: State | AZ |
| Site Address: Postal Code | 85712 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 5 |
| Date of submission (Pre-filled from custom function) | 09/APR/2021 10:04 |
| 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

US3192734 (Prod: Quality of Life Medical and Research Center - Hunt - PPDS)

US3192734

Form: Participant Creation

Generated On: 09 Jun 2021 15:38:11

[Participant ID](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'US3192734' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 04 Oct 2020 20:22:34 |

US3192734

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:38:11

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Saysamone Banks (b) (4) | 04 Oct 2020 21:17:12 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '04 OCT 2020' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 04 Oct 2020 20:22:36 |

US3192734

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Clinic (Clinic)' | Saysamone Banks (b) (4) | 04 Oct 2020 21:17:12 |

US3192734

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:38:11

[Folder OID](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered 'SCRN' | System | 04 Oct 2020 21:17:12 |

US3192734

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:38:11

Date of Birth (MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered (b) (6) 1962' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 04 Oct 2020 20:22:37 |

US3192734

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:38:11

[Age](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered '58' | (b) (4) Saysamone Banks (b) (4) | 04 Oct 2020 21:17:33 |

US3192734

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:38:11

[Age Units](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered 'YEARS' | System | 04 Oct 2020 21:17:33 |

US3192734

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:38:11

[Age \(Derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered '58' | System | 04 Oct 2020 21:17:42 |

US3192734

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:38:11

[Sex](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered 'Female (F)' | (b) (4) Saysamone Banks (b) (4) | 04 Oct 2020 21:17:33 |

US3192734

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:38:11

[Ethnicity](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | (b) (4) Saysamone Banks (b) (4) | 04 Oct 2020 21:17:33 |

US3192734

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:38:11

[White](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered '0' | Saysamone Banks (b) (4) | 04 Oct 2020 21:17:33 |

US3192734

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:38:11

[Black](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered 'I' | Saysamone Banks (b) (4) | 04 Oct 2020 21:17:33 |

US3192734

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:38:11

[Asian](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered '0' | Saysamone Banks (b) (4) | 04 Oct 2020 21:17:33 |

US3192734

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:38:11

[American Indian or Alaska Native](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered '0' | Saysamone Banks (b) (4) | 04 Oct 2020 21:17:33 |

US3192734

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:38:11

[Native Hawaiian or other Pacific Islander](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered '0' | Saysamone Banks (b) (4) | 04 Oct 2020 21:17:33 |

US3192734

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:38:11

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered '0' | Saysamone Banks (b) (4) | 04 Oct 2020 21:17:33 |

US3192734

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:38:11

[If race is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered empty. | (b) (4) | |
| | Saysamone Banks (b) (4) | 04 Oct 2020 21:17:33 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:38:11

[Unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered '0' | Saysamone Banks (b) (4) | 04 Oct 2020 21:17:33 |

US3192734

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:38:11

[Not reported](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered '0' | Saysamone Banks (b) (4) | 04 Oct 2020 21:17:33 |

US3192734

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered '4 Oct 2020' | (b) (4) | |
| | Saysamone Banks (b) (4) | 04 Oct 2020 21:17:42 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered 'Oct 2020' | System | 04 Oct 2020 21:17:42 |

US3192734

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered '2020' | System | 04 Oct 2020 21:17:42 |

US3192734

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:38:11

[Protocol Version](#)

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered 'Amendment 3 (3)' | Saysamone Banks (b) (4) | 04 Oct 2020 21:17:42 |

US3192734

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Saysamone Banks (b) (4) | 04 Oct 2020 21:17:42 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered empty. | (b) (4) | |
| | Saysamone Banks (b) (4) | 04 Oct 2020 21:17:42 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:38:11

If reason for screen fail is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered empty. | (b) (4) | |
| | Saysamone Banks (b) (4) | 04 Oct 2020 21:17:42 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:38:11

[Was this participant screened previously?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered 'No (N)' | (b) (4) | |
| | Saysamone Banks (b) (4) | 04 Oct 2020 21:17:42 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:38:11

[If Yes, previous participant number](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered empty. | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 04 Oct 2020 20:22:36 |

US3192734

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:38:11

[Enrollment Trigger](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered 'I' | System | 04 Oct 2020 21:17:46 |

US3192734

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Saysamone Banks (b) (4) | 04 Oct 2020 21:17:46 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:38:11

[Were any significant conditions reported?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Saysamone Banks (b) (4) | 05 Oct 2020 18:50:48 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:38:11

[Condition](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User coded data point as SOC: Cardiac disorders, HLT: Supraventricular arrhythmias, PT: Sinus tachycardia, LLT: Sinus tachycardia - version MedDRA\\23.0. | Coder Import (b) (4) | 05 Oct 2020 18:53:25 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 05 Oct 2020 18:53:25 |
| Data point term sent to Coder | System | 05 Oct 2020 18:52:13 |
| User entered 'sinus tachycardia' | Saysamone Banks (b) (4) | 05 Oct 2020 18:51:13 |

US3192734

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'un Jun 2019' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 18:51:13 |

US3192734

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:38:11

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '0' | Saysamone Banks (b) (4) | 05 Oct 2020 18:51:13 |

US3192734

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:38:11

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Saysamone Banks (b) (4) | 05 Oct 2020 18:51:13 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered empty. | (b) (4) | |
| | Saysamone Banks (b) (4) | 05 Oct 2020 18:51:13 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:38:11

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '0' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 18:51:13 |

US3192734

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered 'Jun 2019' | System | 05 Oct 2020 18:51:13 |

US3192734

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered '2019' | System | 05 Oct 2020 18:51:13 |

US3192734

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered empty. | System | 05 Oct 2020 18:51:13 |

US3192734

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered empty. | System | 05 Oct 2020 18:51:13 |

US3192734

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:38:11

[Condition](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0. | Coder Import (b) (4) | 05 Oct 2020 18:53:25 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 05 Oct 2020 18:53:25 |
| Data point term sent to Coder | System | 05 Oct 2020 18:52:13 |
| User entered 'anxiety' | Saysamone Banks (b) (4) | 05 Oct 2020 18:51:49 |

US3192734

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'un Mar 2020' | Saysamone Banks (b) (4) | 05 Oct 2020 18:51:49 |

US3192734

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:38:11

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '0' | Saysamone Banks (b) (4) | 05 Oct 2020 18:51:49 |

US3192734

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:38:11

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Yes (Y)' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 18:51:49 |

US3192734

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered empty. | (b) (4) | |
| | Saysamone Banks (b) (4) | 05 Oct 2020 18:51:49 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:38:11

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '0' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 18:51:49 |

US3192734

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered 'Mar 2020' | System | 05 Oct 2020 18:51:49 |

US3192734

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered '2020' | System | 05 Oct 2020 18:51:49 |

US3192734

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered empty. | System | 05 Oct 2020 18:51:49 |

US3192734

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered empty. | System | 05 Oct 2020 18:51:49 |

US3192734

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:38:11

[Condition](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0. | Coder Import (b) (4) | 05 Oct 2020 18:53:25 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 05 Oct 2020 18:53:25 |
| Data point term sent to Coder | System | 05 Oct 2020 18:52:13 |
| User entered 'depression' | Saysamone Banks (b) (4) | 05 Oct 2020 18:52:05 |

US3192734

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'un Mar 2020' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 18:52:05 |

US3192734

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:38:11

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '0' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 18:52:05 |

US3192734

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:38:11

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Yes (Y)' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 18:52:05 |

US3192734

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered empty. | (b) (4) | |
| | Saysamone Banks (b) (4) | 05 Oct 2020 18:52:05 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:38:11

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '0' | Saysamone Banks (b) (4) | 05 Oct 2020 18:52:05 |

US3192734

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered 'Mar 2020' | System | 05 Oct 2020 18:52:05 |

US3192734

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered '2020' | System | 05 Oct 2020 18:52:05 |

US3192734

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered empty. | System | 05 Oct 2020 18:52:05 |

US3192734

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered empty. | System | 05 Oct 2020 18:52:05 |

US3192734

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:38:11

Condition

| Audit | User | Time (GMT) |
|---|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Lower respiratory tract disorders (excl obstruction and infection), HLT: Parenchymal lung disorders NEC, PT: Pulmonary fibrosis, LLT: Pulmonary fibrosis - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 30 Mar 2021 13:23:57 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 30 Mar 2021 13:23:57 |
| User signature succeeded. | John McGettigan (b) (4) (b) (4) | 20 Mar 2021 17:06:58 |
| Data point term sent to Coder | System | 16 Mar 2021 17:38:28 |
| Coding entries removed. | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:37:46 |
| Signature has been broken. | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:37:46 |
| User entered 'OBSTRUCTIVE AIRWAY LIMITATION/chronic pulmonary fibrosis' reason for change: Data Entry Error | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:37:46 |
| User signature succeeded. | John McGettigan (b) (4) (b) (4) | 14 Feb 2021 03:28:23 |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Obstructive airways disorder, LLT: Obstructive airways disorder - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 25 Nov 2020 06:29:12 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 25 Nov 2020 06:29:12 |
| Data point term sent to Coder | System | 05 Oct 2020 18:53:14 |
| User entered 'obstructive airway limitation' | Saysamone Banks (b) (4) (b) (4) | 05 Oct 2020 18:52:26 |

US3192734

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'un Jun 1999' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 18:52:26 |

US3192734

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:38:11

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '0' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 18:52:26 |

US3192734

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:38:11

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Saysamone Banks (b) (4) | 05 Oct 2020 18:52:26 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered empty. | (b) (4) | |
| | Saysamone Banks (b) (4) | 05 Oct 2020 18:52:26 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:38:11

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '0' | (b) (4) | |
| | Saysamone Banks (b) (4) | 05 Oct 2020 18:52:26 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered 'Jun 1999' | System | 05 Oct 2020 18:52:26 |

US3192734

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered '1999' | System | 05 Oct 2020 18:52:26 |

US3192734

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered empty. | System | 05 Oct 2020 18:52:26 |

US3192734

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered empty. | System | 05 Oct 2020 18:52:26 |

US3192734

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:38:11

[Condition](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Deafness bilateral, LLT: Hearing loss bilateral - version MedDRA\\23.0. | Coder Import (b) (4) | 05 Oct 2020 18:54:29 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 05 Oct 2020 18:54:29 |
| Data point term sent to Coder | System | 05 Oct 2020 18:53:16 |
| User entered 'bilateral hearing loss' | Saysamone Banks (b) (4) | 05 Oct 2020 18:52:44 |

US3192734

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'un Oct 2019' | (b) (4) | |
| | Saysamone Banks (b) (4) | 05 Oct 2020 18:52:44 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:38:11

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '0' | Saysamone Banks (b) (4) | 05 Oct 2020 18:52:44 |

US3192734

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:38:11

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Yes (Y)' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 18:52:44 |

US3192734

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered empty. | (b) (4) | |
| | Saysamone Banks (b) (4) | 05 Oct 2020 18:52:44 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:38:11

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '0' | Saysamone Banks (b) (4) | 05 Oct 2020 18:52:44 |

US3192734

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered 'Oct 2019' | System | 05 Oct 2020 18:52:44 |

US3192734

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered '2019' | System | 05 Oct 2020 18:52:44 |

US3192734

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered empty. | System | 05 Oct 2020 18:52:44 |

US3192734

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered empty. | System | 05 Oct 2020 18:52:44 |

US3192734

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:38:11

Condition

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| 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) | 05 Oct 2020 18:54:27 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 05 Oct 2020 18:54:27 |
| Data point term sent to Coder | System | 05 Oct 2020 18:53:17 |
| User entered 'hypertension' | Saysamone Banks (b) (4) | 05 Oct 2020 18:53:12 |

US3192734

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'un Sep 2019' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 18:53:12 |

US3192734

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:38:11

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '0' | Saysamone Banks (b) (4) | 05 Oct 2020 18:53:12 |

US3192734

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:38:11

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Yes (Y)' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 18:53:12 |

US3192734

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered empty. | Saysamone Banks (b) (4) | 05 Oct 2020 18:53:12 |

US3192734

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:38:11

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '0' | Saysamone Banks (b) (4) | 05 Oct 2020 18:53:12 |

US3192734

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered 'Sep 2019' | System | 05 Oct 2020 18:53:12 |

US3192734

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered '2019' | System | 05 Oct 2020 18:53:12 |

US3192734

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered empty. | System | 05 Oct 2020 18:53:12 |

US3192734

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered empty. | System | 05 Oct 2020 18:53:12 |

US3192734

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:38:11

Condition

| Audit | User | Time (GMT) |
|--|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Fibroids - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) (b) (4) | 05 Oct 2020 18:55:18 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 05 Oct 2020 18:55:18 |
| Data point term sent to Coder | System | 05 Oct 2020 18:54:19 |
| User entered 'fibroids' | Saysamone Banks (b) (4) (b) (4) | 05 Oct 2020 18:53:32 |

US3192734

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'un UNK 2012' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 18:53:32 |

US3192734

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:38:11

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '0' | Saysamone Banks (b) (4) | 05 Oct 2020 18:53:32 |

US3192734

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:38:11

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'No (N)' | (b) (4) | |
| | Saysamone Banks (b) (4) | 05 Oct 2020 18:53:32 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'un UNK 2012' | Saysamone Banks (b) (4) | 05 Oct 2020 18:53:32 |

US3192734

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:38:11

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '0' | Saysamone Banks (b) (4) | 05 Oct 2020 18:53:32 |

US3192734

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered 'Jan 2012' | System | 05 Oct 2020 18:53:32 |

US3192734

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered '2012' | System | 05 Oct 2020 18:53:32 |

US3192734

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered 'Jan 2012' | System | 05 Oct 2020 18:53:32 |

US3192734

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered '2012' | System | 05 Oct 2020 18:53:32 |

US3192734

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:38:11

[Condition](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Gallstones - version MedDRA\\23.0. | Coder Import (b) (4) | 05 Oct 2020 18:55:18 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 05 Oct 2020 18:55:18 |
| Data point term sent to Coder | System | 05 Oct 2020 18:54:22 |
| User entered 'gallstones' | Saysamone Banks (b) (4) | 05 Oct 2020 18:53:49 |

US3192734

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'un UNK 2001' | Saysamone Banks (b) (4) | 05 Oct 2020 18:53:49 |

US3192734

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:38:11

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '0' | Saysamone Banks (b) (4) | 05 Oct 2020 18:53:49 |

US3192734

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:38:11

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'No (N)' | (b) (4) | |
| | Saysamone Banks (b) (4) | 05 Oct 2020 18:53:49 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'un UNK 2001' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 18:53:49 |

US3192734

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:38:11

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '0' | Saysamone Banks (b) (4) | 05 Oct 2020 18:53:49 |

US3192734

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered 'Jan 2001' | System | 05 Oct 2020 18:53:49 |

US3192734

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered '2001' | System | 05 Oct 2020 18:53:49 |

US3192734

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered 'Jan 2001' | System | 05 Oct 2020 18:53:49 |

US3192734

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered '2001' | System | 05 Oct 2020 18:53:49 |

US3192734

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:38:11

[Condition](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms malignant and unspecified (incl nipple), HLT: Breast and nipple neoplasms malignant, PT: Breast cancer, LLT: Breast cancer - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) | 05 Oct 2020 18:55:18 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 05 Oct 2020 18:55:18 |
| Data point term sent to Coder | System | 05 Oct 2020 18:54:22 |
| User entered 'left breast cancer' | Saysamone Banks (b) (4) | 05 Oct 2020 18:54:09 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'un UNK 2008' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 18:54:09 |

US3192734

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:38:11

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '0' | Saysamone Banks (b) (4) | 05 Oct 2020 18:54:09 |

US3192734

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:38:11

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'No (N)' | (b) (4) | |
| | Saysamone Banks (b) (4) | 05 Oct 2020 18:54:09 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'un UNK 2008' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 18:54:09 |

US3192734

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:38:11

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '0' | Saysamone Banks (b) (4) | 05 Oct 2020 18:54:09 |

US3192734

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered 'Jan 2008' | System | 05 Oct 2020 18:54:09 |

US3192734

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered '2008' | System | 05 Oct 2020 18:54:09 |

US3192734

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered 'Jan 2008' | System | 05 Oct 2020 18:54:09 |

US3192734

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered '2008' | System | 05 Oct 2020 18:54:09 |

US3192734

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:38:11

Condition

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Lymphomas Hodgkin's disease, HLT: Hodgkin's disease NEC, PT: Hodgkin's disease, LLT: Hodgkin's lymphoma - version MedDRA\\23.0. | Coder Import (b) (4) | 05 Oct 2020 18:58:28 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 05 Oct 2020 18:58:28 |
| Data point term sent to Coder | System | 05 Oct 2020 18:57:27 |
| User entered 'Hodgkin's lymphoma' | Saysamone Banks (b) (4) | 05 Oct 2020 18:56:59 |

US3192734

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'un UNK 1999' | Saysamone Banks (b) (4) | 05 Oct 2020 18:56:59 |

US3192734

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:38:11

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '0' | Saysamone Banks (b) (4) | 05 Oct 2020 18:56:59 |

US3192734

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:38:11

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'No (N)' | (b) (4) | |
| | Saysamone Banks (b) (4) | 05 Oct 2020 18:56:59 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'un UNK 1999' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 18:56:59 |

US3192734

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:38:11

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '0' | Saysamone Banks (b) (4) | 05 Oct 2020 18:56:59 |

US3192734

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered 'Jan 1999' | System | 05 Oct 2020 18:56:59 |

US3192734

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered '1999' | System | 05 Oct 2020 18:56:59 |

US3192734

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered 'Jan 1999' | System | 05 Oct 2020 18:56:59 |

US3192734

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered '1999' | System | 05 Oct 2020 18:56:59 |

US3192734

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:38:11

[Condition](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Breast therapeutic procedures, HLT: Mastectomies, PT: Mastectomy, LLT: Mastectomy - version MedDRA\\23.0. | Coder Import (b) (4) | 05 Oct 2020 18:59:18 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 05 Oct 2020 18:59:18 |
| Data point term sent to Coder | System | 05 Oct 2020 18:58:28 |
| User entered 'left mastectomy' | Saysamone Banks (b) (4) | 05 Oct 2020 18:57:48 |

US3192734

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'un UNK 2008' | Saysamone Banks (b) (4) | 05 Oct 2020 18:57:48 |

US3192734

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:38:11

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '0' | Saysamone Banks (b) (4) | 05 Oct 2020 18:57:48 |

US3192734

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:38:11

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'No (N)' | (b) (4) | |
| | Saysamone Banks (b) (4) | 05 Oct 2020 18:57:48 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'un UNK 2008' | Saysamone Banks (b) (4) | 05 Oct 2020 18:57:48 |

US3192734

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:38:11

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '0' | Saysamone Banks (b) (4) | 05 Oct 2020 18:57:48 |

US3192734

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered 'Jan 2008' | System | 05 Oct 2020 18:57:48 |

US3192734

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered '2008' | System | 05 Oct 2020 18:57:48 |

US3192734

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered 'Jan 2008' | System | 05 Oct 2020 18:57:48 |

US3192734

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered '2008' | System | 05 Oct 2020 18:57:48 |

US3192734

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:38:11

Condition

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0. | Coder Import (b) (4) | 05 Oct 2020 18:59:19 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 05 Oct 2020 18:59:19 |
| Data point term sent to Coder | System | 05 Oct 2020 18:58:28 |
| User entered 'hysterectomy' | Saysamone Banks (b) (4) | 05 Oct 2020 18:58:27 |

US3192734

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'un UNK 2012' | Saysamone Banks (b) (4) | 05 Oct 2020 18:58:27 |

US3192734

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:38:11

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '0' | Saysamone Banks (b) (4) | 05 Oct 2020 18:58:27 |

US3192734

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:38:11

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'No (N)' | (b) (4) | |
| | Saysamone Banks (b) (4) | 05 Oct 2020 18:58:27 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'un UNK 2012' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 18:58:27 |

US3192734

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:38:11

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '0' | Saysamone Banks (b) (4) | 05 Oct 2020 18:58:27 |

US3192734

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered 'Jan 2012' | System | 05 Oct 2020 18:58:27 |

US3192734

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered '2012' | System | 05 Oct 2020 18:58:27 |

US3192734

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered 'Jan 2012' | System | 05 Oct 2020 18:58:27 |

US3192734

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered '2012' | System | 05 Oct 2020 18:58:27 |

US3192734

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:38:11

Condition

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0. | Coder Import (b) (4) | 05 Oct 2020 19:00:20 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 05 Oct 2020 19:00:20 |
| Data point term sent to Coder | System | 05 Oct 2020 18:59:29 |
| User entered 'cholecystectomy' | Saysamone Banks (b) (4) | 05 Oct 2020 18:58:53 |

US3192734

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'un UNK 2001' | Saysamone Banks (b) (4) | 05 Oct 2020 18:58:53 |

US3192734

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:38:11

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '0' | Saysamone Banks (b) (4) | 05 Oct 2020 18:58:53 |

US3192734

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:38:11

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'No (N)' | (b) (4) | |
| | Saysamone Banks (b) (4) | 05 Oct 2020 18:58:53 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'un UNK 2001' | Saysamone Banks (b) (4) | 05 Oct 2020 18:58:53 |

US3192734

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:38:11

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '0' | Saysamone Banks (b) (4) | 05 Oct 2020 18:58:53 |

US3192734

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered 'Jan 2001' | System | 05 Oct 2020 18:58:53 |

US3192734

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered '2001' | System | 05 Oct 2020 18:58:53 |

US3192734

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered 'Jan 2001' | System | 05 Oct 2020 18:58:53 |

US3192734

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered '2001' | System | 05 Oct 2020 18:58:53 |

US3192734

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:38:11

[Condition](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0. | Coder Import (b) (4) | 05 Oct 2020 19:00:20 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 05 Oct 2020 19:00:20 |
| Data point term sent to Coder | System | 05 Oct 2020 18:59:30 |
| User entered 'insomnia' | Saysamone Banks (b) (4) | 05 Oct 2020 18:59:06 |

US3192734

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'un UNK 2018' | Saysamone Banks (b) (4) | 05 Oct 2020 18:59:06 |

US3192734

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:38:11

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '0' | Saysamone Banks (b) (4) | 05 Oct 2020 18:59:06 |

US3192734

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:38:11

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Saysamone Banks (b) (4) | 05 Oct 2020 18:59:06 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered empty. | (b) (4) | |
| | Saysamone Banks (b) (4) | 05 Oct 2020 18:59:06 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:38:11

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '0' | Saysamone Banks (b) (4) | 05 Oct 2020 18:59:06 |

US3192734

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered 'Jan 2018' | System | 05 Oct 2020 18:59:06 |

US3192734

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered '2018' | System | 05 Oct 2020 18:59:06 |

US3192734

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered empty. | System | 05 Oct 2020 18:59:06 |

US3192734

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered empty. | System | 05 Oct 2020 18:59:06 |

US3192734

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:38:11

[Condition](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Radiotherapies site unspecified, PT: Radiotherapy, LLT: Radiation therapy - version MedDRA\\23.0. | Coder Import (b) (4) | 08 Apr 2021 06:24:45 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 08 Apr 2021 06:24:45 |
| Data point term sent to Coder | System | 08 Apr 2021 02:53:41 |
| User entered 'Radiation for lymphoma' | Yvonne De Los Reyes (b) (4) | 08 Apr 2021 02:53:12 |

US3192734

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'un UNK 1999' | Yvonne De Los Reyes (b) (4) | 08 Apr 2021 02:53:12 |

US3192734

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:38:11

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Yvonne De Los Reyes (b) (4) | 08 Apr 2021 02:53:12 |

US3192734

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:38:11

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | (b) (4) Yvonne De Los Reyes (b) (4) | 08 Apr 2021 02:53:12 |

US3192734

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'un UNK 1999' | Yvonne De Los Reyes (b) (4) | 08 Apr 2021 02:53:12 |

US3192734

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:38:11

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Yvonne De Los Reyes (b) (4) | 08 Apr 2021 02:53:12 |

US3192734

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered 'Jan 1999' | System | 08 Apr 2021 02:53:12 |

US3192734

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered '1999' | System | 08 Apr 2021 02:53:12 |

US3192734

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered 'Jan 1999' | System | 08 Apr 2021 02:53:12 |

US3192734

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered '1999' | System | 08 Apr 2021 02:53:12 |

US3192734

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Saysamone Banks (b) (4) | 05 Oct 2020 16:13:07 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '4 Oct 2020' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 16:13:07 |

US3192734

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '14:39' | (b) (4) | |
| | Saysamone Banks (b) (4) | 05 Oct 2020 16:13:07 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered '4 Oct 2020 14:39' | System | 05 Oct 2020 16:13:07 |

US3192734

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '67' in | (b) (4) | |
| | Saysamone Banks (b) (4) | 05 Oct 2020 16:13:07 |
| DataPoint set to visible. | (b) (4) | |
| | System | 04 Oct 2020 21:17:46 |

US3192734

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '174.8' lb | (b) (4) | |
| | Saysamone Banks (b) (4) | 05 Oct 2020 16:13:07 |
| DataPoint set to visible. | (b) (4) | |
| | System | 04 Oct 2020 21:17:46 |

US3192734

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered '27.43479' | System | 05 Oct 2020 16:13:07 |
| DataPoint set to visible. | System | 04 Oct 2020 21:17:46 |

US3192734

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[BMI units](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered 'kg/m2' | System | 05 Oct 2020 16:13:07 |
| DataPoint set to visible. | System | 04 Oct 2020 21:17:46 |

US3192734

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered missing code ND - Not Done. | (b) (4) | |
| | Saysamone Banks (b) (4) | 05 Oct 2020 16:13:07 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered empty. | (b) (4) | |
| | Saysamone Banks (b) (4) | 05 Oct 2020 16:13:07 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered empty. | (b) (4) | |
| | Saysamone Banks (b) (4) | 05 Oct 2020 16:13:07 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered missing code ND - Not Done. | (b) (4) | |
| | Saysamone Banks (b) (4) | 05 Oct 2020 16:13:07 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered 'bpm' | System | 05 Oct 2020 16:13:07 |

US3192734

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered missing code ND - Not Done. | (b) (4) | |
| | Saysamone Banks (b) (4) | 05 Oct 2020 16:13:07 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered 'breaths/min' | System | 05 Oct 2020 16:13:07 |

US3192734

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered missing code ND - Not Done. | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 16:13:07 |

US3192734

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered 'mmHg' | System | 05 Oct 2020 16:13:07 |

US3192734

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered missing code ND - Not Done. | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 16:13:07 |

US3192734

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User entered 'mmHg' | System | 05 Oct 2020 16:13:07 |

US3192734

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| | | |

US3192734

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Weight \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| | | |

US3192734

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:38:11

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Saysamone Banks (b) (4) | 04 Oct 2020 21:19:54 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:38:11

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '4 Oct 2020' | (b) (4) | |
| | Saysamone Banks (b) (4) | 04 Oct 2020 21:19:54 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:38:11

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered '4 Oct 2020' | (b) (4) Saysamone Banks (b) (4) | 04 Oct 2020 21:20:17 |

US3192734

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered 'No (N)' | (b) (4) | |
| | Saysamone Banks (b) (4) | 04 Oct 2020 21:20:17 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered 'Surgically sterile (SURGICALLY STERILE)' | (b) (4) Saysamone Banks (b) (4) | 04 Oct 2020 21:20:17 |

US3192734

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered empty. | (b) (4) | |
| | Saysamone Banks (b) (4) | 04 Oct 2020 21:20:17 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered 'un UNK 2012' | Saysamone Banks (b) (4) | 04 Oct 2020 21:20:17 |

US3192734

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:38:11

[Date of surgery unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered '0' | (b) (4) Saysamone Banks (b) (4) | 04 Oct 2020 21:20:17 |

US3192734

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered empty. | Saysamone Banks (b) (4) | 04 Oct 2020 21:20:17 |

US3192734

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:38:11

[Date of last menstruation unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered '0' | Saysamone Banks (b) (4) | 04 Oct 2020 21:20:17 |

US3192734

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'No (N)' | (b) (4) Saysamone Banks (b) (4) | 04 Oct 2020 21:20:38 |

US3192734

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'No (N)' | (b) (4) Saysamone Banks (b) (4) | 04 Oct 2020 21:20:38 |

US3192734

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:38:11

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) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'No (N)' | (b) (4) Saysamone Banks (b) (4) | 04 Oct 2020 21:20:38 |

US3192734

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:38:11

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) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'No (N)' | Saysamone Banks (b) (4) | 04 Oct 2020 21:20:38 |

US3192734

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:38:11

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'No (N)' | (b) (4) Saysamone Banks (b) (4) | 04 Oct 2020 21:20:38 |

US3192734

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:38:11

[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) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'No (N)' | (b) (4) Saysamone Banks (b) (4) | 04 Oct 2020 21:20:38 |

US3192734

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:38:11

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) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'No (N)' | Saysamone Banks (b) (4) | 04 Oct 2020 21:20:38 |

US3192734

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:38:11

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) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'No (N)' | (b) (4) Saysamone Banks (b) (4) | 04 Oct 2020 21:20:38 |

US3192734

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:38:11

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) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'No (N)' | (b) (4) | |
| | Saysamone Banks (b) (4) | 04 Oct 2020 21:20:38 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:38:11

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) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'No (N)' | (b) (4) Saysamone Banks (b) (4) | 04 Oct 2020 21:20:38 |

US3192734

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:38:11

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) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'No (N)' | (b) (4) Saysamone Banks (b) (4) | 04 Oct 2020 21:20:38 |

US3192734

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:38:11

Other

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'No (N)' | (b) (4) | |
| | Saysamone Banks (b) (4) | 04 Oct 2020 21:20:38 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:38:11

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered empty. | (b) (4) | |
| | Saysamone Banks (b) (4) | 04 Oct 2020 21:20:38 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:38:11

No Risk Identified

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '0' | (b) (4) | |
| | Saysamone Banks (b) (4) | 04 Oct 2020 21:20:38 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:38:11

Resides in Nursing Home or Assisted Living Facility

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '0' | Saysamone Banks (b) (4) | 04 Oct 2020 21:20:38 |

US3192734

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:38:11

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) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '0' | Saysamone Banks (b) (4) | 04 Oct 2020 21:20:38 |

US3192734

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:38:11

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) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '0' | (b) (4) Saysamone Banks (b) (4) | 04 Oct 2020 21:20:38 |

US3192734

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:38:11

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) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '0' | (b) (4) Saysamone Banks (b) (4) | 04 Oct 2020 21:20:38 |

US3192734

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'I' | (b) (4) | |
| | Saysamone Banks (b) (4) | 04 Oct 2020 21:20:38 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:38:11

Other

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '0' | (b) (4) | |
| | Saysamone Banks (b) (4) | 04 Oct 2020 21:20:38 |
| | (b) (4) | |

US3192734

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:38:11

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:46:23 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered empty. | (b) (4) | |
| | Saysamone Banks (b) (4) | 04 Oct 2020 21:20:38 |
| | (b) (4) | |

US3192734

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:38:11

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Yes (Y)' | Saysamone Banks (b) (4) | 04 Oct 2020 21:20:52 |

US3192734

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '4 Oct 2020' | Saysamone Banks (b) (4) | 04 Oct 2020 21:20:52 |

US3192734

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Clinic (Clinic)' | Saysamone Banks (b) (4) | 04 Oct 2020 21:20:52 |

US3192734

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:38:11

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered 'VISIT1' | System | 04 Oct 2020 21:20:52 |

US3192734

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '04 OCT 2020' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 04 Oct 2020 20:27:34 |

US3192734

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '146890' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 04 Oct 2020 20:27:34 |

US3192734

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '>=18 and <65 years and at risk (2)' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 04 Oct 2020 20:27:34 |

US3192734

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:38:11

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) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Yes (Y)' | (b) (4) Saysamone Banks (b) (4) | 04 Oct 2020 21:21:25 |

US3192734

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:38:11

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) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'No (N)' | Saysamone Banks (b) (4) | 04 Oct 2020 21:21:25 |

US3192734

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'No (N)' | (b) (4) Saysamone Banks (b) (4) | 04 Oct 2020 21:21:25 |

US3192734

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:38:11

[Diabetes \(Type I, Type 2, or gestational\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'No (N)' | (b) (4) Saysamone Banks (b) (4) | 04 Oct 2020 21:21:25 |

US3192734

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:38:11

[Liver Disease](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'No (N)' | (b) (4) Saysamone Banks (b) (4) | 04 Oct 2020 21:21:25 |

US3192734

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'No (N)' | (b) (4) | |
| | Saysamone Banks (b) (4) | 04 Oct 2020 21:21:25 |
| DataPoint set to visible. | (b) (4) | |
| | System | 04 Oct 2020 21:17:42 |

US3192734

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:38:11

[Height](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered missing code ND - Not Done. | (b) (4) | |
| | Saysamone Banks (b) (4) | 05 Oct 2020 16:30:12 |
| | (b) (4) | |

US3192734

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:38:11

[Weight](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered missing code ND - Not Done. | (b) (4) | |
| | Saysamone Banks (b) (4) | 05 Oct 2020 16:30:12 |
| | (b) (4) | |

US3192734

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:38:11

[Height](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered missing code ND - Not Done. | (b) (4) | |
| | Saysamone Banks (b) (4) | 05 Oct 2020 16:30:12 |
| | (b) (4) | |

US3192734

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:38:11

[Weight](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered missing code ND - Not Done. | (b) (4) | |
| | Saysamone Banks (b) (4) | 05 Oct 2020 16:30:12 |
| | (b) (4) | |

US3192734

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Saysamone Banks (b) (4) | 05 Oct 2020 16:30:12 |
| | (b) (4) | |

US3192734

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Yes (Y)' | Saysamone Banks (b) (4) | 05 Oct 2020 16:30:12 |

US3192734

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '4 Oct 2020' | (b) (4) | |
| | Saysamone Banks (b) (4) | 05 Oct 2020 16:30:12 |
| | (b) (4) | |

US3192734

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '12:14' | (b) (4) | |
| | Saysamone Banks (b) (4) | 05 Oct 2020 16:30:12 |
| | (b) (4) | |

US3192734

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered '4 Oct 2020 12:14' | System | 05 Oct 2020 16:30:12 |

US3192734

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '98.9' F | Saysamone Banks (b) (4) | 05 Oct 2020 16:30:12 |

US3192734

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Oral (Oral)' | (b) (4) | |
| | Saysamone Banks (b) (4) | 05 Oct 2020 16:30:12 |
| | (b) (4) | |

US3192734

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered empty. | Saysamone Banks (b) (4) | 05 Oct 2020 16:30:12 |

US3192734

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '67' | Saysamone Banks (b) (4) | 05 Oct 2020 16:30:12 |

US3192734

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered 'bpm' | System | 05 Oct 2020 16:30:12 |

US3192734

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '14' | Saysamone Banks (b) (4) | 05 Oct 2020 16:30:12 |

US3192734

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered 'breaths/min' | System | 05 Oct 2020 16:30:12 |

US3192734

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '121' | Saysamone Banks (b) (4) | 05 Oct 2020 16:30:12 |

US3192734

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered 'mmHg' | System | 05 Oct 2020 16:30:12 |

US3192734

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '82' | Saysamone Banks (b) (4) | 05 Oct 2020 16:30:12 |

US3192734

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered 'mmHg' | System | 05 Oct 2020 16:30:12 |

US3192734

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:38:11

[Height](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered missing code ND - Not Done. | (b) (4) | |
| | Saysamone Banks (b) (4) | 05 Oct 2020 16:30:12 |
| | (b) (4) | |

US3192734

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:38:11

[Weight](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered missing code ND - Not Done. | (b) (4) | |
| | Saysamone Banks (b) (4) | 05 Oct 2020 16:30:12 |
| | (b) (4) | |

US3192734

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Saysamone Banks (b) (4) | 05 Oct 2020 16:32:59 |
| | (b) (4) | |

US3192734

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Saysamone Banks (b) (4) | 05 Oct 2020 16:32:59 |
| | (b) (4) | |

US3192734

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '4 Oct 2020' | (b) (4) | |
| | Saysamone Banks (b) (4) | 05 Oct 2020 16:32:59 |
| | (b) (4) | |

US3192734

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '14:39' | Saysamone Banks (b) (4) | 05 Oct 2020 16:32:59 |

US3192734

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered '4 Oct 2020 14:39' | System | 05 Oct 2020 16:32:59 |

US3192734

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '97.8' F | Saysamone Banks (b) (4) | 05 Oct 2020 16:32:59 |

US3192734

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Oral (Oral)' | Saysamone Banks (b) (4) | 05 Oct 2020 16:32:59 |

US3192734

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered empty. | Saysamone Banks (b) (4) | 05 Oct 2020 16:32:59 |

US3192734

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '73' | Saysamone Banks (b) (4) | 05 Oct 2020 16:32:59 |

US3192734

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered 'bpm' | System | 05 Oct 2020 16:32:59 |

US3192734

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '10' | Saysamone Banks (b) (4) | 05 Oct 2020 16:32:59 |

US3192734

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered 'breaths/min' | System | 05 Oct 2020 16:32:59 |

US3192734

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '114' | Saysamone Banks (b) (4) | 05 Oct 2020 16:32:59 |

US3192734

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered 'mmHg' | System | 05 Oct 2020 16:32:59 |

US3192734

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '78' | Saysamone Banks (b) (4) | 05 Oct 2020 16:32:59 |

US3192734

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered 'mmHg' | System | 05 Oct 2020 16:32:59 |

US3192734

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:38:11

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'No (N)' | Saysamone Banks (b) (4) | 04 Oct 2020 21:21:30 |

US3192734

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:38:11

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered empty. | Saysamone Banks (b) (4) | 04 Oct 2020 21:21:30 |

US3192734

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:38:11

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Saysamone Banks (b) (4) | 04 Oct 2020 21:21:45 |
| | (b) (4) | |

US3192734

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:38:11

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered empty. | Saysamone Banks (b) (4) | 04 Oct 2020 21:21:45 |

US3192734

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered empty. | (b) (4) | |
| | Saysamone Banks (b) (4) | 04 Oct 2020 21:21:45 |
| | (b) (4) | |

US3192734

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:38:11

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:38:11

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '4 Oct 2020' | (b) (4) Saysamone Banks (b) (4) | 04 Oct 2020 21:21:45 |

US3192734

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '14:09' | Saysamone Banks (b) (4) | 04 Oct 2020 21:21:45 |

US3192734

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered '4 Oct 2020 14:09' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|------------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Left Arm (LEFT ARM)' | Saysamone Banks (b) (4) | 04 Oct 2020 21:21:45 |

US3192734

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered 'ONCE' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:38:11

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered 'INTRAMUSCULAR' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:11

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Yes (Y)' | (b) (4) Saysamone Banks (b) (4) | 04 Oct 2020 21:21:57 |

US3192734

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:11

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '4 Oct 2020' | (b) (4) Saysamone Banks (b) (4) | 04 Oct 2020 21:21:57 |

US3192734

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:11

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '13:59' | (b) (4) Saysamone Banks (b) (4) | 04 Oct 2020 21:21:57 |

US3192734

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered '4 Oct 2020 13:59' | System | 04 Oct 2020 21:21:57 |

US3192734

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:38:11

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '4 Oct 2020' | (b) (4) Saysamone Banks (b) (4) | 04 Oct 2020 21:22:11 |

US3192734

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:38:11

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Saysamone Banks (b) (4) | 04 Oct 2020 21:22:11 |

US3192734

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:38:11

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Yes (Y)' | (b) (4) Saysamone Banks (b) (4) | 04 Oct 2020 21:22:11 |

US3192734

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:38:11

[Collection time \(00:00 - 23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '13:55' | (b) (4) | |
| | Saysamone Banks (b) (4) | 04 Oct 2020 21:22:11 |
| | (b) (4) | |

US3192734

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered '4 Oct 2020 13:55' | System | 04 Oct 2020 21:22:11 |

US3192734

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:38:11

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Saysamone Banks (b) (4) | 04 Oct 2020 21:22:11 |

US3192734

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:38:11

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'No (N)' | (b) (4) Saysamone Banks (b) (4) | 04 Oct 2020 21:22:11 |

US3192734

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:38:11

[Collection time \(00:00 - 23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered empty. | (b) (4) | |
| | Saysamone Banks (b) (4) | 04 Oct 2020 21:22:11 |
| | (b) (4) | |

US3192734

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered empty. | System | 04 Oct 2020 21:22:11 |

US3192734

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Saysamone Banks (b) (4) | 04 Oct 2020 21:22:16 |
| | (b) (4) | |

US3192734

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:38:11

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered 'I' | System | 04 Oct 2020 21:22:16 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 04 Oct 2020 21:21:45 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-04T14:48:13', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'ed501c68-44e4-4a38-8c12-a0644e854abd' User entered 'Yes (Y)' | System | 04 Oct 2020 21:48:52 |
| | System | 04 Oct 2020 21:48:52 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-04T14:48:19', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'ed501c68-44e4-4a38-8c12-a0644e854abd' User entered '97.8' | System | 04 Oct 2020 21:48:52 |
| | System | 04 Oct 2020 21:48:52 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-04T14:48:24', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'ed501c68-44e4-4a38-8c12-a0644e854abd' User entered 'No (N)' | System | 04 Oct 2020 21:48:52 |
| | System | 04 Oct 2020 21:48:52 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-04T14:48:49', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'ed501c68-44e4-4a38-8c12-a0644e854abd' User entered '04 Oct 2020 14:48' | System | 04 Oct 2020 21:48:52 |
| | System | 04 Oct 2020 21:48:52 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '04 Oct 2020 14:29' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '04 Oct 2020 16:59' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 04 Oct 2020 21:21:45 |
| User entered 'Day 1, after vaccination (at home)' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-04T21:32:29', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '04e11d12-2840-4f0b-a774-6ebe477eb229' User entered 'Yes (Y)' | System | 05 Oct 2020 04:32:51 |
| | System | 05 Oct 2020 04:32:51 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-04T21:32:35', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '04e11d12-2840-4f0b-a774-6ebe477eb229' User entered '96.9' | System | 05 Oct 2020 04:32:51 |
| | System | 05 Oct 2020 04:32:51 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-04T21:32:40', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '04e11d12-2840-4f0b-a774-6ebe477eb229' User entered 'No (N)' | System | 05 Oct 2020 04:32:51 |
| | System | 05 Oct 2020 04:32:51 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-04T21:32:45', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '04e11d12-2840-4f0b-a774-6ebe477eb229' User entered '04 Oct 2020 21:32' | System | 05 Oct 2020 04:32:51 |
| | System | 05 Oct 2020 04:32:51 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '04 Oct 2020 17:54' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '05 Oct 2020 11:59' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 04 Oct 2020 21:21:45 |
| User entered 'Day 2' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:38:11

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-05T21:40:27', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '15bad7a1-e571-4344-8425-73cedcd153df' User entered 'Yes (Y)' | System | 06 Oct 2020 04:40:49 |
| | System | 06 Oct 2020 04:40:49 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:38:11

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-05T21:40:37', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '15bad7a1-e571-4344-8425-73cedcd153df' User entered '96.5' | System | 06 Oct 2020 04:40:49 |
| | System | 06 Oct 2020 04:40:49 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:38:11

Was any MEDICATION TAKEN today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-05T21:40:41', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '15bad7a1-e571-4344-8425-73cedcd153df' User entered 'No (N)' | System | 06 Oct 2020 04:40:49 |
| | System | 06 Oct 2020 04:40:49 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-05T21:40:47', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '15bad7a1-e571-4344-8425-73cedcd153df' User entered '05 Oct 2020 21:40' | System | 06 Oct 2020 04:40:49 |
| | System | 06 Oct 2020 04:40:49 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '05 Oct 2020 12:00' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '06 Oct 2020 11:59' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 04 Oct 2020 21:21:45 |
| User entered 'Day 3' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:38:11

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-06T21:57:46', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '76ef64e6-d3f5-4310-a293-0ed1361af542' | System | 07 Oct 2020 04:58:10 |
| User entered 'Yes (Y)' | System | 07 Oct 2020 04:58:10 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:38:11

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-06T21:57:57', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '76ef64e6-d3f5-4310-a293-0ed1361af542' | System | 07 Oct 2020 04:58:10 |
| User entered '96.0' | System | 07 Oct 2020 04:58:10 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-06T21:58:02', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '76ef64e6-d3f5-4310-a293-0ed1361af542' | System | 07 Oct 2020 04:58:10 |
| User entered 'No (N)' | System | 07 Oct 2020 04:58:10 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-06T21:58:07', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '76ef64e6-d3f5-4310-a293-0ed1361af542' | System | 07 Oct 2020 04:58:10 |
| User entered '06 Oct 2020 21:58' | System | 07 Oct 2020 04:58:10 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '06 Oct 2020 12:00' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '07 Oct 2020 11:59' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 04 Oct 2020 21:21:45 |
| User entered 'Day 4' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:38:11

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-07T19:54:02', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '3d4f6814-d660-416a-b2e4-ba9d33910178' User entered 'Yes (Y)' | System | 08 Oct 2020 02:54:18 |
| | System | 08 Oct 2020 02:54:18 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:38:11

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-07T19:54:08', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '3d4f6814-d660-416a-b2e4-ba9d33910178' User entered '97.9' | System | 08 Oct 2020 02:54:18 |
| | System | 08 Oct 2020 02:54:18 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-07T19:54:11', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '3d4f6814-d660-416a-b2e4-ba9d33910178' User entered 'No (N)' | System | 08 Oct 2020 02:54:18 |
| | System | 08 Oct 2020 02:54:18 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-07T19:54:14', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '3d4f6814-d660-416a-b2e4-ba9d33910178' User entered '07 Oct 2020 19:54' | System | 08 Oct 2020 02:54:18 |
| | System | 08 Oct 2020 02:54:18 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '07 Oct 2020 12:00' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '08 Oct 2020 11:59' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 04 Oct 2020 21:21:45 |
| User entered 'Day 5' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:38:11

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-08T22:19:58', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'ae352960-7d02-432f-9712-cde66c5ab54a' User entered 'Yes (Y)' | System | 09 Oct 2020 05:20:16 |
| | System | 09 Oct 2020 05:20:16 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:38:11

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-08T22:20:05', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'ae352960-7d02-432f-9712-cde66c5ab54a' User entered '96.9' | System | 09 Oct 2020 05:20:16 |
| | System | 09 Oct 2020 05:20:16 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-08T22:20:10', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'ae352960-7d02-432f-9712-cde66c5ab54a' | System | 09 Oct 2020 05:20:16 |
| User entered 'No (N)' | System | 09 Oct 2020 05:20:16 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-08T22:20:15', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'ae352960-7d02-432f-9712-cde66c5ab54a' User entered '08 Oct 2020 22:20' | System | 09 Oct 2020 05:20:16 |
| | System | 09 Oct 2020 05:20:16 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '08 Oct 2020 12:00' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '09 Oct 2020 11:59' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 04 Oct 2020 21:21:45 |
| User entered 'Day 6' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:38:11

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-09T17:53:34', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '41b4f1a1-e0f1-437b-8f50-471ef163eef6' User entered 'Yes (Y)' | System | 10 Oct 2020 00:53:49 |
| | System | 10 Oct 2020 00:53:49 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:38:11

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-09T17:53:38', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '41b4f1a1-e0f1-437b-8f50-471ef163eef6' User entered '97.7' | System | 10 Oct 2020 00:53:49 |
| | System | 10 Oct 2020 00:53:49 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-09T17:53:41', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '41b4f1a1-e0f1-437b-8f50-471ef163eef6' | System | 10 Oct 2020 00:53:49 |
| User entered 'No (N)' | System | 10 Oct 2020 00:53:49 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-09T17:53:46', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '41b4f1a1-e0f1-437b-8f50-471ef163eef6' User entered '09 Oct 2020 17:53' | System | 10 Oct 2020 00:53:49 |
| | System | 10 Oct 2020 00:53:49 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '09 Oct 2020 12:00' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '10 Oct 2020 11:59' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 04 Oct 2020 21:21:45 |
| User entered 'Day 7' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:38:11

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-10T22:00:02', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'b8988900-185d-4de4-b81e-14b4868bd266' | System | 11 Oct 2020 05:00:18 |
| User entered 'Yes (Y)' | System | 11 Oct 2020 05:00:18 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:38:11

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-10T22:00:07', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'b8988900-185d-4de4-b81e-14b4868bd266' | System | 11 Oct 2020 05:00:18 |
| User entered '96.8' | System | 11 Oct 2020 05:00:18 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-10T22:00:10', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'b8988900-185d-4de4-b81e-14b4868bd266' | System | 11 Oct 2020 05:00:18 |
| User entered 'No (N)' | System | 11 Oct 2020 05:00:18 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-10T22:00:14', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'b8988900-185d-4de4-b81e-14b4868bd266' User entered '10 Oct 2020 22:00' | System | 11 Oct 2020 05:00:18 |
| | System | 11 Oct 2020 05:00:18 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '10 Oct 2020 12:00' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '11 Oct 2020 11:59' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 04 Oct 2020 21:21:45 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-04T14:49:01', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '36ef5abf-d5d9-49f6-8756-db2b68bfbebf' User entered 'None (1)' | System | 04 Oct 2020 21:49:24 |
| | System | 04 Oct 2020 21:49:24 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-04T14:49:08', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '36ef5abf-d5d9-49f6-8756-db2b68bfbebf' User entered 'No (N)' | System | 04 Oct 2020 21:49:24 |
| | System | 04 Oct 2020 21:49:24 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-04T14:49:13', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '36ef5abf-d5d9-49f6-8756-db2b68bfbebf' User entered 'No (N)' | System | 04 Oct 2020 21:49:24 |
| | System | 04 Oct 2020 21:49:24 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-04T14:49:17', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '36ef5abf-d5d9-49f6-8756-db2b68bfbebf' User entered 'None (1)' | System | 04 Oct 2020 21:49:24 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-04T14:49:22', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '36ef5abf-d5d9-49f6-8756-db2b68bfbebf' User entered '04 Oct 2020 14:49' | System | 04 Oct 2020 21:49:24 |
| | System | 04 Oct 2020 21:49:24 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '04 Oct 2020 14:29' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '04 Oct 2020 16:59' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 04 Oct 2020 21:21:45 |
| User entered 'Day 1, after vaccination (at home)' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-04T21:32:51', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '8cf00845-0694-42f5-9dc8-e2d18310af7a' User entered 'None (1)' | System | 05 Oct 2020 04:33:13 |
| | System | 05 Oct 2020 04:33:13 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-04T21:32:54', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '8cf00845-0694-42f5-9dc8-e2d18310af7a' User entered 'No (N)' | System | 05 Oct 2020 04:33:13 |
| | System | 05 Oct 2020 04:33:13 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-04T21:32:59', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '8cf00845-0694-42f5-9dc8-e2d18310af7a' User entered 'No (N)' | System | 05 Oct 2020 04:33:13 |
| | System | 05 Oct 2020 04:33:13 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-04T21:33:04', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '8cf00845-0694-42f5-9dc8-e2d18310af7a' User entered 'None (1)' | System | 05 Oct 2020 04:33:13 |
| | System | 05 Oct 2020 04:33:13 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-04T21:33:10', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '8cf00845-0694-42f5-9dc8-e2d18310af7a' User entered '04 Oct 2020 21:33' | System | 05 Oct 2020 04:33:13 |
| | System | 05 Oct 2020 04:33:13 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '04 Oct 2020 17:54' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '05 Oct 2020 11:59' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 04 Oct 2020 21:21:45 |
| User entered 'Day 2' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-05T21:40:55', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '75def856-f8e2-4df6-a984-68fb83789a9d' | System | 06 Oct 2020 04:41:19 |
| User entered 'None (1)' | System | 06 Oct 2020 04:41:19 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-05T21:41:04', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '75def856-f8e2-4df6-a984-68fb83789a9d' | System | 06 Oct 2020 04:41:19 |
| User entered 'No (N)' | System | 06 Oct 2020 04:41:19 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-05T21:41:06', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '75def856-f8e2-4df6-a984-68fb83789a9d' | System | 06 Oct 2020 04:41:19 |
| User entered 'No (N)' | System | 06 Oct 2020 04:41:19 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-05T21:41:11', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '75def856-f8e2-4df6-a984-68fb83789a9d' | System | 06 Oct 2020 04:41:19 |
| User entered 'None (1)' | System | 06 Oct 2020 04:41:19 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-05T21:41:15', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '75def856-f8e2-4df6-a984-68fb83789a9d' User entered '05 Oct 2020 21:41' | System | 06 Oct 2020 04:41:19 |
| | System | 06 Oct 2020 04:41:19 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '05 Oct 2020 12:00' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '06 Oct 2020 11:59' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 04 Oct 2020 21:21:45 |
| User entered 'Day 3' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-06T21:58:19', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'cbbcf450-1118-40bc-9ee9-13fbe51b5a2f' User entered 'None (1)' | System | 07 Oct 2020 04:58:31 |
| | System | 07 Oct 2020 04:58:31 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-06T21:58:21', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'cbbcf450-1118-40bc-9ee9-13fbe51b5a2f' User entered 'No (N)' | System | 07 Oct 2020 04:58:31 |
| | System | 07 Oct 2020 04:58:31 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-06T21:58:24', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'cbbcf450-1118-40bc-9ee9-13fbe51b5a2f' User entered 'No (N)' | System | 07 Oct 2020 04:58:31 |
| | System | 07 Oct 2020 04:58:31 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-06T21:58:26', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'cbbcf450-1118-40bc-9ee9-13fbe51b5a2f' User entered 'None (1)' | System | 07 Oct 2020 04:58:31 |
| | System | 07 Oct 2020 04:58:31 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-06T21:58:29', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'cbbcf450-1118-40bc-9ee9-13fbe51b5a2f' User entered '06 Oct 2020 21:58' | System | 07 Oct 2020 04:58:31 |
| | System | 07 Oct 2020 04:58:31 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '06 Oct 2020 12:00' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '07 Oct 2020 11:59' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 04 Oct 2020 21:21:45 |
| User entered 'Day 4' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-07T19:54:17', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '44d36335-0dd7-4884-9d8b-d6905824ad0c' | System | 08 Oct 2020 02:54:30 |
| User entered 'None (1)' | System | 08 Oct 2020 02:54:30 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-07T19:54:20', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '44d36335-0dd7-4884-9d8b-d6905824ad0c' User entered 'No (N)' | System | 08 Oct 2020 02:54:30 |
| | System | 08 Oct 2020 02:54:30 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-07T19:54:23', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '44d36335-0dd7-4884-9d8b-d6905824ad0c' User entered 'No (N)' | System | 08 Oct 2020 02:54:30 |
| | System | 08 Oct 2020 02:54:30 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-07T19:54:25', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '44d36335-0dd7-4884-9d8b-d6905824ad0c' User entered 'None (1)' | System | 08 Oct 2020 02:54:30 |
| | System | 08 Oct 2020 02:54:30 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-07T19:54:28', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '44d36335-0dd7-4884-9d8b-d6905824ad0c' User entered '07 Oct 2020 19:54' | System | 08 Oct 2020 02:54:30 |
| | System | 08 Oct 2020 02:54:30 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '07 Oct 2020 12:00' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '08 Oct 2020 11:59' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 04 Oct 2020 21:21:45 |
| User entered 'Day 5' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-08T22:20:21', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '30ac6512-430f-45ec-8408-abe5a1d614f0' | System | 09 Oct 2020 05:20:47 |
| User entered 'None (1)' | System | 09 Oct 2020 05:20:47 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-08T22:20:28', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '30ac6512-430f-45ec-8408-abe5a1d614f0' User entered 'No (N)' | System | 09 Oct 2020 05:20:47 |
| | System | 09 Oct 2020 05:20:47 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-08T22:20:36', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '30ac6512-430f-45ec-8408-abe5a1d614f0' User entered 'No (N)' | System | 09 Oct 2020 05:20:47 |
| | System | 09 Oct 2020 05:20:47 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-08T22:20:40', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '30ac6512-430f-45ec-8408-abe5a1d614f0' User entered 'None (1)' | System | 09 Oct 2020 05:20:47 |
| | System | 09 Oct 2020 05:20:47 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-08T22:20:43', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '30ac6512-430f-45ec-8408-abe5a1d614f0' User entered '08 Oct 2020 22:20' | System | 09 Oct 2020 05:20:47 |
| | System | 09 Oct 2020 05:20:47 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '08 Oct 2020 12:00' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '09 Oct 2020 11:59' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 04 Oct 2020 21:21:45 |
| User entered 'Day 6' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-09T17:53:50', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '121ea95b-4fd2-4e9b-bb73-e5af38b0bc04' User entered 'None (1)' | System | 10 Oct 2020 00:54:03 |
| | System | 10 Oct 2020 00:54:03 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-09T17:53:52', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '121ea95b-4fd2-4e9b-bb73-e5af38b0bc04' User entered 'No (N)' | System | 10 Oct 2020 00:54:03 |
| | System | 10 Oct 2020 00:54:03 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-09T17:53:55', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '121ea95b-4fd2-4e9b-bb73-e5af38b0bc04' User entered 'No (N)' | System | 10 Oct 2020 00:54:03 |
| | System | 10 Oct 2020 00:54:03 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-09T17:53:57', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '121ea95b-4fd2-4e9b-bb73-e5af38b0bc04' User entered 'None (1)' | System | 10 Oct 2020 00:54:03 |
| | System | 10 Oct 2020 00:54:03 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-09T17:54:00', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '121ea95b-4fd2-4e9b-bb73-e5af38b0bc04' User entered '09 Oct 2020 17:54' | System | 10 Oct 2020 00:54:03 |
| | System | 10 Oct 2020 00:54:03 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '09 Oct 2020 12:00' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '10 Oct 2020 11:59' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 04 Oct 2020 21:21:45 |
| User entered 'Day 7' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-10T22:00:18', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'dbae642f-7bf6-4d30-a945-4ae778bcf372' | System | 11 Oct 2020 05:00:34 |
| User entered 'None (1)' | System | 11 Oct 2020 05:00:34 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-10T22:00:21', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'dbae642f-7bf6-4d30-a945-4ae778bcf372' | System | 11 Oct 2020 05:00:34 |
| User entered 'No (N)' | System | 11 Oct 2020 05:00:34 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-10T22:00:23', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'dbae642f-7bf6-4d30-a945-4ae778bcf372' | System | 11 Oct 2020 05:00:34 |
| User entered 'No (N)' | System | 11 Oct 2020 05:00:34 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-10T22:00:25', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'dbae642f-7bf6-4d30-a945-4ae778bcf372' | System | 11 Oct 2020 05:00:34 |
| User entered 'None (1)' | System | 11 Oct 2020 05:00:34 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-10T22:00:33', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'dbae642f-7bf6-4d30-a945-4ae778bcf372' | System | 11 Oct 2020 05:00:34 |
| User entered '10 Oct 2020 22:00' | System | 11 Oct 2020 05:00:34 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '10 Oct 2020 12:00' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '11 Oct 2020 11:59' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 04 Oct 2020 21:21:45 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-04T14:49:30', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'a19d6356-7f8f-402a-b5c9-886176db01c7' User entered 'None (0)' | System | 04 Oct 2020 21:49:57 |
| | System | 04 Oct 2020 21:49:57 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-04T14:49:33', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'a19d6356-7f8f-402a-b5c9-886176db01c7' User entered 'None (0)' | System | 04 Oct 2020 21:49:57 |
| | System | 04 Oct 2020 21:49:57 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-04T14:49:36', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'a19d6356-7f8f-402a-b5c9-886176db01c7' User entered 'None (0)' | System | 04 Oct 2020 21:49:57 |
| | System | 04 Oct 2020 21:49:57 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-04T14:49:39', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'a19d6356-7f8f-402a-b5c9-886176db01c7' User entered 'None (0)' | System | 04 Oct 2020 21:49:57 |
| | System | 04 Oct 2020 21:49:57 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-04T14:49:42', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'a19d6356-7f8f-402a-b5c9-886176db01c7' User entered 'None (0)' | System | 04 Oct 2020 21:49:57 |
| | System | 04 Oct 2020 21:49:57 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-04T14:49:44', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'a19d6356-7f8f-402a-b5c9-886176db01c7' User entered 'None (0)' | System | 04 Oct 2020 21:49:57 |
| | System | 04 Oct 2020 21:49:57 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-04T14:49:49', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'a19d6356-7f8f-402a-b5c9-886176db01c7' User entered 'No (N)' | System | 04 Oct 2020 21:49:57 |
| | System | 04 Oct 2020 21:49:57 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-04T14:49:52', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'a19d6356-7f8f-402a-b5c9-886176db01c7' User entered '04 Oct 2020 14:49' | System | 04 Oct 2020 21:49:57 |
| | System | 04 Oct 2020 21:49:57 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '04 Oct 2020 14:29' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '04 Oct 2020 16:59' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 04 Oct 2020 21:21:45 |
| User entered 'Day 1, after vaccination (at home)' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-04T21:33:19', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '5bfbc700-1ba7-46ef-b700-b513e4f8e78c' User entered 'None (0)' | System | 05 Oct 2020 04:33:42 |
| | System | 05 Oct 2020 04:33:42 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-04T21:33:23', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '5bfbc700-1ba7-46ef-b700-b513e4f8e78c' User entered 'None (0)' | System | 05 Oct 2020 04:33:42 |
| | System | 05 Oct 2020 04:33:42 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-04T21:33:25', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '5bfbc700-1ba7-46ef-b700-b513e4f8e78c' User entered 'None (0)' | System | 05 Oct 2020 04:33:42 |
| | System | 05 Oct 2020 04:33:42 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-04T21:33:28', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '5bfbc700-1ba7-46ef-b700-b513e4f8e78c' User entered 'None (0)' | System | 05 Oct 2020 04:33:42 |
| | System | 05 Oct 2020 04:33:42 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-04T21:33:29', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '5bfbc700-1ba7-46ef-b700-b513e4f8e78c' User entered 'None (0)' | System | 05 Oct 2020 04:33:42 |
| | System | 05 Oct 2020 04:33:42 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-04T21:33:31', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '5bfbc700-1ba7-46ef-b700-b513e4f8e78c' User entered 'None (0)' | System | 05 Oct 2020 04:33:42 |
| | System | 05 Oct 2020 04:33:42 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-04T21:33:36', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '5bfbc700-1ba7-46ef-b700-b513e4f8e78c' User entered 'No (N)' | System | 05 Oct 2020 04:33:42 |
| | System | 05 Oct 2020 04:33:42 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-04T21:33:40', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '5bfbc700-1ba7-46ef-b700-b513e4f8e78c' User entered '04 Oct 2020 21:33' | System | 05 Oct 2020 04:33:42 |
| | System | 05 Oct 2020 04:33:42 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '04 Oct 2020 17:54' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '05 Oct 2020 11:59' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 04 Oct 2020 21:21:45 |
| User entered 'Day 2' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:11

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-05T21:41:20', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '2933bc32-7873-45fa-8164-4d1e5e626e8f' User entered 'None (0)' | System | 06 Oct 2020 04:41:42 |
| | System | 06 Oct 2020 04:41:42 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:11

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-05T21:41:23', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '2933bc32-7873-45fa-8164-4d1e5e626e8f' User entered 'None (0)' | System | 06 Oct 2020 04:41:42 |
| | System | 06 Oct 2020 04:41:42 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:11

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-05T21:41:25', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '2933bc32-7873-45fa-8164-4d1e5e626e8f' User entered 'None (0)' | System | 06 Oct 2020 04:41:42 |
| | System | 06 Oct 2020 04:41:42 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:11

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-05T21:41:28', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '2933bc32-7873-45fa-8164-4d1e5e626e8f' User entered 'None (0)' | System | 06 Oct 2020 04:41:42 |
| | System | 06 Oct 2020 04:41:42 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:11

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-05T21:41:30', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '2933bc32-7873-45fa-8164-4d1e5e626e8f' User entered 'None (0)' | System | 06 Oct 2020 04:41:42 |
| | System | 06 Oct 2020 04:41:42 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:11

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-05T21:41:32', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '2933bc32-7873-45fa-8164-4d1e5e626e8f' User entered 'None (0)' | System | 06 Oct 2020 04:41:42 |
| | System | 06 Oct 2020 04:41:42 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-05T21:41:37', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '2933bc32-7873-45fa-8164-4d1e5e626e8f' User entered 'No (N)' | System | 06 Oct 2020 04:41:42 |
| | System | 06 Oct 2020 04:41:42 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-05T21:41:41', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '2933bc32-7873-45fa-8164-4d1e5e626e8f' User entered '05 Oct 2020 21:41' | System | 06 Oct 2020 04:41:42 |
| | System | 06 Oct 2020 04:41:42 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '05 Oct 2020 12:00' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '06 Oct 2020 11:59' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 04 Oct 2020 21:21:45 |
| User entered 'Day 3' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:11

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-06T21:58:33', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'c58cb386-d406-42b1-84ac-da0ed6ee1ca8' User entered 'None (0)' | System | 07 Oct 2020 04:58:58 |
| | System | 07 Oct 2020 04:58:58 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:11

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-06T21:58:35', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'c58cb386-d406-42b1-84ac-da0ed6ee1ca8' User entered 'None (0)' | System | 07 Oct 2020 04:58:58 |
| | System | 07 Oct 2020 04:58:58 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:11

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-06T21:58:37', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'c58cb386-d406-42b1-84ac-da0ed6ee1ca8' User entered 'None (0)' | System | 07 Oct 2020 04:58:58 |
| | System | 07 Oct 2020 04:58:58 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:11

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-06T21:58:40', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'c58cb386-d406-42b1-84ac-da0ed6ee1ca8' User entered 'None (0)' | System | 07 Oct 2020 04:58:58 |
| | System | 07 Oct 2020 04:58:58 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:11

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-06T21:58:42', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'c58cb386-d406-42b1-84ac-da0ed6ee1ca8' User entered 'None (0)' | System | 07 Oct 2020 04:58:58 |
| | System | 07 Oct 2020 04:58:58 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:11

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-06T21:58:44', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'c58cb386-d406-42b1-84ac-da0ed6ee1ca8' User entered 'None (0)' | System | 07 Oct 2020 04:58:58 |
| | System | 07 Oct 2020 04:58:58 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-06T21:58:47', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'c58cb386-d406-42b1-84ac-da0ed6ee1ca8' User entered 'No (N)' | System | 07 Oct 2020 04:58:58 |
| | System | 07 Oct 2020 04:58:58 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-06T21:58:52', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'c58cb386-d406-42b1-84ac-da0ed6ee1ca8' User entered '06 Oct 2020 21:58' | System | 07 Oct 2020 04:58:58 |
| | System | 07 Oct 2020 04:58:58 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '06 Oct 2020 12:00' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '07 Oct 2020 11:59' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 04 Oct 2020 21:21:45 |
| User entered 'Day 4' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:11

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-07T19:54:47', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '4615ed91-3357-4ef5-9701-49bcee84d9b6' | System | 08 Oct 2020 02:55:11 |
| User entered 'No interference with activity (1)' | System | 08 Oct 2020 02:55:11 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:11

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-07T19:54:49', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '4615ed91-3357-4ef5-9701-49bcee84d9b6' User entered 'None (0)' | System | 08 Oct 2020 02:55:11 |
| | System | 08 Oct 2020 02:55:11 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:11

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-07T19:54:52', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '4615ed91-3357-4ef5-9701-49bcee84d9b6' User entered 'None (0)' | System | 08 Oct 2020 02:55:11 |
| | System | 08 Oct 2020 02:55:11 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:11

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-07T19:54:54', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '4615ed91-3357-4ef5-9701-49bcee84d9b6' User entered 'None (0)' | System | 08 Oct 2020 02:55:11 |
| | System | 08 Oct 2020 02:55:11 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:11

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-07T19:54:56', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '4615ed91-3357-4ef5-9701-49bcee84d9b6' User entered 'None (0)' | System | 08 Oct 2020 02:55:11 |
| | System | 08 Oct 2020 02:55:11 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:11

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-07T19:54:58', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '4615ed91-3357-4ef5-9701-49bcee84d9b6' User entered 'None (0)' | System | 08 Oct 2020 02:55:11 |
| | System | 08 Oct 2020 02:55:11 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-07T19:55:01', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '4615ed91-3357-4ef5-9701-49bcee84d9b6' User entered 'No (N)' | System | 08 Oct 2020 02:55:11 |
| | System | 08 Oct 2020 02:55:11 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-07T19:55:09', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '4615ed91-3357-4ef5-9701-49bcee84d9b6' User entered '07 Oct 2020 19:55' | System | 08 Oct 2020 02:55:11 |
| | System | 08 Oct 2020 02:55:11 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '07 Oct 2020 12:00' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '08 Oct 2020 11:59' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 04 Oct 2020 21:21:45 |
| User entered 'Day 5' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:11

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-08T22:20:47', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '2322b2c5-861e-4e9c-8595-f4e1483bfd43' User entered 'None (0)' | System | 09 Oct 2020 05:21:07 |
| | System | 09 Oct 2020 05:21:07 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:11

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-08T22:20:49', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '2322b2c5-861e-4e9c-8595-f4e1483bfd43' User entered 'None (0)' | System | 09 Oct 2020 05:21:07 |
| | System | 09 Oct 2020 05:21:07 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:11

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-08T22:20:52', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '2322b2c5-861e-4e9c-8595-f4e1483bfd43' User entered 'None (0)' | System | 09 Oct 2020 05:21:07 |
| | System | 09 Oct 2020 05:21:07 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:11

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-08T22:20:53', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '2322b2c5-861e-4e9c-8595-f4e1483bfd43' User entered 'None (0)' | System | 09 Oct 2020 05:21:07 |
| | System | 09 Oct 2020 05:21:07 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:11

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-08T22:20:55', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '2322b2c5-861e-4e9c-8595-f4e1483bfd43' User entered 'None (0)' | System | 09 Oct 2020 05:21:07 |
| | System | 09 Oct 2020 05:21:07 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:11

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-08T22:20:57', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '2322b2c5-861e-4e9c-8595-f4e1483bfd43' User entered 'None (0)' | System | 09 Oct 2020 05:21:07 |
| | System | 09 Oct 2020 05:21:07 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-08T22:21:01', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '2322b2c5-861e-4e9c-8595-f4e1483bfd43' User entered 'No (N)' | System | 09 Oct 2020 05:21:07 |
| | System | 09 Oct 2020 05:21:07 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-08T22:21:04', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '2322b2c5-861e-4e9c-8595-f4e1483bfd43' User entered '08 Oct 2020 22:21' | System | 09 Oct 2020 05:21:07 |
| | System | 09 Oct 2020 05:21:07 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '08 Oct 2020 12:00' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '09 Oct 2020 11:59' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 04 Oct 2020 21:21:45 |
| User entered 'Day 6' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:11

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-09T17:54:03', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'f7e71e73-60d8-4696-819c-8362aa0d179d' User entered 'None (0)' | System | 10 Oct 2020 00:54:21 |
| | System | 10 Oct 2020 00:54:21 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:11

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-09T17:54:06', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'f7e71e73-60d8-4696-819c-8362aa0d179d' User entered 'None (0)' | System | 10 Oct 2020 00:54:21 |
| | System | 10 Oct 2020 00:54:21 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:11

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-09T17:54:07', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'f7e71e73-60d8-4696-819c-8362aa0d179d' User entered 'None (0)' | System | 10 Oct 2020 00:54:21 |
| | System | 10 Oct 2020 00:54:21 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:11

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-09T17:54:10', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'f7e71e73-60d8-4696-819c-8362aa0d179d' User entered 'None (0)' | System | 10 Oct 2020 00:54:21 |
| | System | 10 Oct 2020 00:54:21 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:11

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-09T17:54:12', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'f7e71e73-60d8-4696-819c-8362aa0d179d' User entered 'None (0)' | System | 10 Oct 2020 00:54:21 |
| | System | 10 Oct 2020 00:54:21 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:11

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-09T17:54:14', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'f7e71e73-60d8-4696-819c-8362aa0d179d' User entered 'None (0)' | System | 10 Oct 2020 00:54:21 |
| | System | 10 Oct 2020 00:54:21 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-09T17:54:16', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'f7e71e73-60d8-4696-819c-8362aa0d179d' User entered 'No (N)' | System | 10 Oct 2020 00:54:21 |
| | System | 10 Oct 2020 00:54:21 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-09T17:54:19', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'f7e71e73-60d8-4696-819c-8362aa0d179d' User entered '09 Oct 2020 17:54' | System | 10 Oct 2020 00:54:21 |
| | System | 10 Oct 2020 00:54:21 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '09 Oct 2020 12:00' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '10 Oct 2020 11:59' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 04 Oct 2020 21:21:45 |
| User entered 'Day 7' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:11

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-10T22:00:36', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '76262b89-8e42-49ac-a5b7-b39e89797d1f' User entered 'None (0)' | System | 11 Oct 2020 05:00:55 |
| | System | 11 Oct 2020 05:00:55 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:11

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-10T22:00:38', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '76262b89-8e42-49ac-a5b7-b39e89797d1f' User entered 'None (0)' | System | 11 Oct 2020 05:00:55 |
| | System | 11 Oct 2020 05:00:55 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:11

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-10T22:00:40', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '76262b89-8e42-49ac-a5b7-b39e89797d1f' User entered 'None (0)' | System | 11 Oct 2020 05:00:55 |
| | System | 11 Oct 2020 05:00:55 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:11

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-10T22:00:42', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '76262b89-8e42-49ac-a5b7-b39e89797d1f' User entered 'None (0)' | System | 11 Oct 2020 05:00:55 |
| | System | 11 Oct 2020 05:00:55 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:11

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-10T22:00:43', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '76262b89-8e42-49ac-a5b7-b39e89797d1f' User entered 'None (0)' | System | 11 Oct 2020 05:00:55 |
| | System | 11 Oct 2020 05:00:55 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:11

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-10T22:00:46', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '76262b89-8e42-49ac-a5b7-b39e89797d1f' User entered 'None (0)' | System | 11 Oct 2020 05:00:55 |
| | System | 11 Oct 2020 05:00:55 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-10T22:00:48', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '76262b89-8e42-49ac-a5b7-b39e89797d1f' User entered 'No (N)' | System | 11 Oct 2020 05:00:55 |
| | System | 11 Oct 2020 05:00:55 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-10-10T22:00:51', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '76262b89-8e42-49ac-a5b7-b39e89797d1f' User entered '10 Oct 2020 22:00' | System | 11 Oct 2020 05:00:55 |
| | System | 11 Oct 2020 05:00:55 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '10 Oct 2020 12:00' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '11 Oct 2020 11:59' | System | 04 Oct 2020 21:21:45 |

US3192734

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered 'Yes (Y)' | Zoe Sesma (b) (4) | 13 Oct 2020 23:06:13 |

US3192734

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| 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) | 13 Oct 2020 23:06:23 |
| 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 by data change (Site from System). | System | 13 Oct 2020 23:06:23 |
| User closed query 'Future date has been entered. Please correct.' (Site from System). | System | 13 Oct 2020 23:06:23 |
| User entered '11 Oct 2020' reason for change: Data Entry Error | Zoe Sesma (b) (4) | 13 Oct 2020 23:06:23 |
| User opened query 'Future date has been entered. Please correct.' (Site from System). | (b) (4) | |
| User opened query 'Future date has been entered. Please correct.' (Site from System). | System | 13 Oct 2020 23:06:13 |
| 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 | 13 Oct 2020 23:06:13 |
| User entered '18 Oct 2020' | Zoe Sesma (b) (4) | 13 Oct 2020 23:06:13 |
| | (b) (4) | |

US3192734

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered 'Contact Made (CONTACT MADE)' | Zoe Sesma (b) (4) | 13 Oct 2020 23:06:13 |

US3192734

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered empty. | Zoe Sesma (b) (4) | 13 Oct 2020 23:06:13 |

US3192734

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered 'Yes (Y)' | Zoe Sesma (b) (4) | 13 Oct 2020 23:06:27 |

US3192734

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:11

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered 'I' | System | 13 Oct 2020 23:06:27 |

US3192734

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 04:11:47 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Oct 2020 23:43:44 |

US3192734

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 04:11:47 |
| User entered '21 Oct 2020' | (b) (4) (b) (4), (b) (6) | 21 Oct 2020 23:43:44 |

US3192734

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 04:11:47 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 21 Oct 2020 23:43:44 |

US3192734

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 04:11:47 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Oct 2020 23:43:44 |

US3192734

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 04:11:47 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Oct 2020 23:43:48 |

US3192734

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:11

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered 'I' | System | 21 Oct 2020 23:43:48 |

US3192734

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 27 Oct 2020 21:26:55 |

US3192734

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered '27 Oct 2020' | (b) (4) (b) (4), (b) (6) | 27 Oct 2020 21:26:55 |

US3192734

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 27 Oct 2020 21:26:55 |

US3192734

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 27 Oct 2020 21:26:55 |

US3192734

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 27 Oct 2020 21:27:01 |

US3192734

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:11

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered 'I' | System | 27 Oct 2020 21:27:01 |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:11

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Saysamone Banks (b) (4) | 02 Nov 2020 19:44:08 |
| | (b) (4) | |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '2 Nov 2020' | (b) (4) | |
| | Saysamone Banks (b) (4) | 02 Nov 2020 19:44:08 |
| | (b) (4) | |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Clinic (Clinic)' | (b) (4) | |
| | Saysamone Banks (b) (4) | 02 Nov 2020 19:44:08 |
| | (b) (4) | |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:11

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered 'VISIT2' | System | 02 Nov 2020 19:44:08 |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Saysamone Banks (b) (4) | 02 Nov 2020 22:19:01 |
| | (b) (4) | |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Saysamone Banks (b) (4) | 02 Nov 2020 22:19:01 |
| | (b) (4) | |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '2 Nov 2020' | (b) (4) | |
| | Saysamone Banks (b) (4) | 02 Nov 2020 22:19:01 |
| | (b) (4) | |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '10:44' | Saysamone Banks (b) (4) | 02 Nov 2020 22:19:01 |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered '2 Nov 2020 10:44' | System | 02 Nov 2020 22:19:01 |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '96.9' F | Saysamone Banks (b) (4) | 02 Nov 2020 22:19:01 |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Oral (Oral)' | (b) (4) | |
| | Saysamone Banks (b) (4) | 02 Nov 2020 22:19:01 |
| | (b) (4) | |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered empty. | (b) (4) | |
| | Saysamone Banks (b) (4) | 02 Nov 2020 22:19:01 |
| | (b) (4) | |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '70' | Saysamone Banks (b) (4) | 02 Nov 2020 22:19:01 |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered 'bpm' | System | 02 Nov 2020 22:19:01 |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '16' | Saysamone Banks (b) (4) | 02 Nov 2020 22:19:01 |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered 'breaths/min' | System | 02 Nov 2020 22:19:01 |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '110' | (b) (4) | |
| | Saysamone Banks (b) (4) | 02 Nov 2020 22:19:01 |
| | (b) (4) | |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered 'mmHg' | System | 02 Nov 2020 22:19:01 |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '67' | Saysamone Banks (b) (4) | 02 Nov 2020 22:19:01 |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered 'mmHg' | System | 02 Nov 2020 22:19:01 |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Saysamone Banks (b) (4) | 02 Nov 2020 22:19:39 |
| | (b) (4) | |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Saysamone Banks (b) (4) | 02 Nov 2020 22:19:39 |
| | (b) (4) | |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '2 Nov 2020' | (b) (4) | |
| | Saysamone Banks (b) (4) | 02 Nov 2020 22:19:39 |
| | (b) (4) | |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '13:07' | (b) (4) | |
| | Saysamone Banks (b) (4) | 02 Nov 2020 22:19:39 |
| | (b) (4) | |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered '2 Nov 2020 13:07' | System | 02 Nov 2020 22:19:39 |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '97.4' F | Saysamone Banks (b) (4) | 02 Nov 2020 22:19:39 |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Oral (Oral)' | (b) (4) | |
| | Saysamone Banks (b) (4) | 02 Nov 2020 22:19:39 |
| | (b) (4) | |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered empty. | (b) (4) | |
| | Saysamone Banks (b) (4) | 02 Nov 2020 22:19:39 |
| | (b) (4) | |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '64' | Saysamone Banks (b) (4) | 02 Nov 2020 22:19:39 |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered 'bpm' | System | 02 Nov 2020 22:19:39 |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '14' | Saysamone Banks (b) (4) | 02 Nov 2020 22:19:39 |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered 'breaths/min' | System | 02 Nov 2020 22:19:39 |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '115' | (b) (4) | |
| | Saysamone Banks (b) (4) | 02 Nov 2020 22:19:39 |
| | (b) (4) | |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered 'mmHg' | System | 02 Nov 2020 22:19:39 |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '71' | (b) (4) | |
| | Saysamone Banks (b) (4) | 02 Nov 2020 22:19:39 |
| | (b) (4) | |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered 'mmHg' | System | 02 Nov 2020 22:19:39 |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:38:11

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Saysamone Banks (b) (4) | 02 Nov 2020 19:44:15 |
| | (b) (4) | |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:38:11

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '2 Nov 2020' | Saysamone Banks (b) (4) | 02 Nov 2020 19:44:15 |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:11

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Saysamone Banks (b) (4) | 02 Nov 2020 19:44:32 |
| | (b) (4) | |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:11

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered empty. | (b) (4) | |
| | Saysamone Banks (b) (4) | 02 Nov 2020 19:44:32 |
| | (b) (4) | |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered empty. | (b) (4) | |
| | Saysamone Banks (b) (4) | 02 Nov 2020 19:44:32 |
| | (b) (4) | |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:11

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:11

[What was the treatment date? \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '2 Nov 2020' | (b) (4) | |
| | Saysamone Banks (b) (4) | 02 Nov 2020 19:44:32 |
| | (b) (4) | |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '12:37' | Saysamone Banks (b) (4) | 02 Nov 2020 19:44:32 |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered '2 Nov 2020 12:37' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|------------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Left Arm (LEFT ARM)' | Saysamone Banks (b) (4) | 02 Nov 2020 19:44:32 |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered 'ONCE' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:11

[What was the route of administration for the study treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered 'INTRAMUSCULAR' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:11

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Saysamone Banks (b) (4) | 02 Nov 2020 19:44:42 |
| | (b) (4) | |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:11

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '2 Nov 2020' | (b) (4) | |
| | Saysamone Banks (b) (4) | 02 Nov 2020 19:44:42 |
| | (b) (4) | |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:11

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '11:13' | (b) (4) | |
| | Saysamone Banks (b) (4) | 02 Nov 2020 19:44:42 |
| | (b) (4) | |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered '2 Nov 2020 11:13' | System | 02 Nov 2020 19:44:42 |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:38:11

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '2 Nov 2020' | (b) (4) | |
| | Saysamone Banks (b) (4) | 02 Nov 2020 19:44:53 |
| | (b) (4) | |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:38:11

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Saysamone Banks (b) (4) | 02 Nov 2020 19:44:53 |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:38:11

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Saysamone Banks (b) (4) | 02 Nov 2020 19:44:53 |
| | (b) (4) | |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:38:11

[Collection time \(00:00 - 23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '11:18' | (b) (4) | |
| | Saysamone Banks (b) (4) | 02 Nov 2020 19:44:53 |
| | (b) (4) | |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered '2 Nov 2020 11:18' | System | 02 Nov 2020 19:44:53 |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:38:11

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Saysamone Banks (b) (4) | 02 Nov 2020 19:44:53 |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:38:11

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'No (N)' | (b) (4) | |
| | Saysamone Banks (b) (4) | 02 Nov 2020 19:44:53 |
| | (b) (4) | |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:38:11

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered empty. | (b) (4) | |
| | Saysamone Banks (b) (4) | 02 Nov 2020 19:44:53 |
| | (b) (4) | |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered empty. | System | 02 Nov 2020 19:44:53 |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Saysamone Banks (b) (4) | 02 Nov 2020 19:44:58 |
| | (b) (4) | |

US3192734

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:11

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered 'I' | System | 02 Nov 2020 19:44:58 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 02 Nov 2020 19:44:32 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-02T13:02:39', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '7859ed85-9405-416c-ab19-4e15a2807097' User entered 'Yes (Y)' | System | 02 Nov 2020 20:03:52 |
| | System | 02 Nov 2020 20:03:52 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-02T13:03:00', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '7859ed85-9405-416c-ab19-4e15a2807097' User entered '97.4' | System | 02 Nov 2020 20:03:52 |
| | System | 02 Nov 2020 20:03:52 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-02T13:03:06', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '7859ed85-9405-416c-ab19-4e15a2807097' | System | 02 Nov 2020 20:03:52 |
| User entered 'No (N)' | System | 02 Nov 2020 20:03:52 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-02T13:03:48', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '7859ed85-9405-416c-ab19-4e15a2807097' User entered '02 Nov 2020 13:03' | System | 02 Nov 2020 20:03:52 |
| | System | 02 Nov 2020 20:03:52 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '02 Nov 2020 12:57' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '02 Nov 2020 15:27' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 02 Nov 2020 19:44:32 |
| User entered 'Day 1, after vaccination (at home)' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-02T20:41:53', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '1530e1b4-7764-481b-9c81-0ef25af71044' User entered 'Yes (Y)' | System | 03 Nov 2020 03:42:11 |
| | System | 03 Nov 2020 03:42:11 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-02T20:41:57', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '1530e1b4-7764-481b-9c81-0ef25af71044' User entered '96.5' | System | 03 Nov 2020 03:42:11 |
| | System | 03 Nov 2020 03:42:11 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-02T20:42:00', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '1530e1b4-7764-481b-9c81-0ef25af71044' | System | 03 Nov 2020 03:42:11 |
| User entered 'No (N)' | System | 03 Nov 2020 03:42:11 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-02T20:42:06', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '1530e1b4-7764-481b-9c81-0ef25af71044' User entered '02 Nov 2020 20:42' | System | 03 Nov 2020 03:42:11 |
| | System | 03 Nov 2020 03:42:11 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '02 Nov 2020 16:22' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '03 Nov 2020 11:59' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 02 Nov 2020 19:44:32 |
| User entered 'Day 2' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:38:11

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-04T07:04:40', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'bd52c0ab-09e5-42b4-8999-678dbfc5696a' User entered 'Yes (Y)' | System | 04 Nov 2020 15:05:09 |
| | System | 04 Nov 2020 15:05:09 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:38:11

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-04T07:04:56', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'bd52c0ab-09e5-42b4-8999-678dbfc5696a' User entered '96.5' | System | 04 Nov 2020 15:05:09 |
| | System | 04 Nov 2020 15:05:09 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-04T07:04:59', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'bd52c0ab-09e5-42b4-8999-678dbfc5696a' User entered 'No (N)' | System | 04 Nov 2020 15:05:09 |
| | System | 04 Nov 2020 15:05:09 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-04T07:05:02', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'bd52c0ab-09e5-42b4-8999-678dbfc5696a' User entered '04 Nov 2020 07:05' | System | 04 Nov 2020 15:05:09 |
| | System | 04 Nov 2020 15:05:09 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '03 Nov 2020 12:00' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '04 Nov 2020 11:59' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 02 Nov 2020 19:44:32 |
| User entered 'Day 3' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:38:11

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-05T04:17:24', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '9b665155-7201-4ced-90b7-a9e4054e22e1' User entered 'Yes (Y)' | System | 05 Nov 2020 12:17:38 |
| | System | 05 Nov 2020 12:17:38 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:38:11

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-05T04:17:28', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '9b665155-7201-4ced-90b7-a9e4054e22e1' User entered '98.7' | System | 05 Nov 2020 12:17:38 |
| | System | 05 Nov 2020 12:17:38 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-05T04:17:31', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '9b665155-7201-4ced-90b7-a9e4054e22e1' User entered 'No (N)' | System | 05 Nov 2020 12:17:38 |
| | System | 05 Nov 2020 12:17:38 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-05T04:17:34', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '9b665155-7201-4ced-90b7-a9e4054e22e1' User entered '05 Nov 2020 04:17' | System | 05 Nov 2020 12:17:38 |
| | System | 05 Nov 2020 12:17:38 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '04 Nov 2020 12:00' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '05 Nov 2020 11:59' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 02 Nov 2020 19:44:32 |
| User entered 'Day 4' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:38:11

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-05T18:10:56', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'c599cc30-00e1-4a3b-b363-6606c88b6611' User entered 'Yes (Y)' | System | 06 Nov 2020 02:11:29 |
| | System | 06 Nov 2020 02:11:29 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:38:11

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-05T18:11:00', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'c599cc30-00e1-4a3b-b363-6606c88b6611' User entered '98.5' | System | 06 Nov 2020 02:11:29 |
| | System | 06 Nov 2020 02:11:29 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-05T18:11:04', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'c599cc30-00e1-4a3b-b363-6606c88b6611' User entered 'Yes (Y)' | System | 06 Nov 2020 02:11:29 |
| | System | 06 Nov 2020 02:11:29 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| 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). | | 12 Nov 2020 07:28:50 |
| 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 'patient confirmed what was taken' (Site from System). | maggie Tono (b) (4) (b) (4) | 06 Nov 2020 21:14:39 |
| 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 | 06 Nov 2020 02:11:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-05T18:11:20', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'c599cc30-00e1-4a3b-b363-6606c88b6611' | System | 06 Nov 2020 02:11:29 |
| User entered '1' | System | 06 Nov 2020 02:11:29 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:38:11

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-05T18:11:20', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'c599cc30-00e1-4a3b-b363-6606c88b6611' User entered '0' | System | 06 Nov 2020 02:11:29 |
| | System | 06 Nov 2020 02:11:29 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-05T18:11:25', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'c599cc30-00e1-4a3b-b363-6606c88b6611' User entered '05 Nov 2020 18:11' | System | 06 Nov 2020 02:11:29 |
| | System | 06 Nov 2020 02:11:29 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '05 Nov 2020 12:00' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '06 Nov 2020 11:59' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 02 Nov 2020 19:44:32 |
| User entered 'Day 5' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:38:11

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-07T07:03:58', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '67de99c2-9861-43c9-a185-7e0ba4e81843' User entered 'Yes (Y)' | System | 07 Nov 2020 15:08:47 |
| | System | 07 Nov 2020 15:08:47 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:38:11

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-07T07:08:23', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '67de99c2-9861-43c9-a185-7e0ba4e81843' User entered '95.4' | System | 07 Nov 2020 15:08:47 |
| | System | 07 Nov 2020 15:08:47 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:38:11

Was any MEDICATION TAKEN today for pain or fever?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-07T07:08:33', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '67de99c2-9861-43c9-a185-7e0ba4e81843' User entered 'Yes (Y)' | System | 07 Nov 2020 15:08:47 |
| | System | 07 Nov 2020 15:08:47 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| 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 'patient verified what was taken for pain ' (Site from System). | | 18 Nov 2020 04:23:47 |
| 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.' | maggie Tono (b) (4) | 09 Nov 2020 17:20:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-07T07:08:40', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '67de99c2-9861-43c9-a185-7e0ba4e81843' | System | 07 Nov 2020 15:08:47 |
| User entered '1' | System | 07 Nov 2020 15:08:47 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:38:11

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-07T07:08:40', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '67de99c2-9861-43c9-a185-7e0ba4e81843' User entered '0' | System | 07 Nov 2020 15:08:47 |
| | System | 07 Nov 2020 15:08:47 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-07T07:08:43', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '67de99c2-9861-43c9-a185-7e0ba4e81843' User entered '07 Nov 2020 07:08' | System | 07 Nov 2020 15:08:47 |
| | System | 07 Nov 2020 15:08:47 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '06 Nov 2020 12:00' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '07 Nov 2020 11:59' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 02 Nov 2020 19:44:32 |
| User entered 'Day 6' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:38:11

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-07T22:26:39', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '839e000f-547c-4b24-949d-dcbb3ac322b3' User entered 'Yes (Y)' | System | 08 Nov 2020 05:27:53 |
| | System | 08 Nov 2020 05:27:53 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:38:11

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-07T22:27:37', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '839e000f-547c-4b24-949d-dcbb3ac322b3' User entered '97.7' | System | 08 Nov 2020 05:27:53 |
| | System | 08 Nov 2020 05:27:53 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-07T22:27:40', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '839e000f-547c-4b24-949d-dcbb3ac322b3' User entered 'Yes (Y)' | System | 08 Nov 2020 05:27:53 |
| | System | 08 Nov 2020 05:27:53 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| 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 'patient confirmed what was take' (Site from System). | | 18 Nov 2020 03:57:59 |
| 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). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-07T22:27:45', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '839e000f-547c-4b24-949d-dcbb3ac322b3' User entered '1' | maggie Tono (b) (4) System | 09 Nov 2020 17:21:51 |
| | System | 08 Nov 2020 05:27:53 |
| | System | 08 Nov 2020 05:27:53 |
| | System | 08 Nov 2020 05:27:53 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:38:11

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-07T22:27:45', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '839e000f-547c-4b24-949d-dcbb3ac322b3' User entered '0' | System | 08 Nov 2020 05:27:53 |
| | System | 08 Nov 2020 05:27:53 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-07T22:27:49', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '839e000f-547c-4b24-949d-dcbb3ac322b3' User entered '07 Nov 2020 22:27' | System | 08 Nov 2020 05:27:53 |
| | System | 08 Nov 2020 05:27:53 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '07 Nov 2020 12:00' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '08 Nov 2020 11:59' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 02 Nov 2020 19:44:32 |
| User entered 'Day 7' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:38:11

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-08T19:06:10', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '6a20d345-b92d-4c7e-b7fb-81e65d326fae' | System | 09 Nov 2020 02:06:41 |
| User entered 'Yes (Y)' | System | 09 Nov 2020 02:06:41 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:38:11

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-08T19:06:19', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '6a20d345-b92d-4c7e-b7fb-81e65d326fae' User entered '99.0' | System | 09 Nov 2020 02:06:41 |
| | System | 09 Nov 2020 02:06:41 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:38:11

Was any MEDICATION TAKEN today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-08T19:06:26', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '6a20d345-b92d-4c7e-b7fb-81e65d326fae' | System | 09 Nov 2020 02:06:41 |
| User entered 'Yes (Y)' | System | 09 Nov 2020 02:06:41 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| 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). | | 18 Nov 2020 04:19:15 |
| 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 'patient confirmed what was taken' (Site from System). | maggie Tono (b) (4) (b) (4) | 09 Nov 2020 17:23:04 |
| 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 | 09 Nov 2020 02:06:41 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-08T19:06:33', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '6a20d345-b92d-4c7e-b7fb-81e65d326fae' | System | 09 Nov 2020 02:06:41 |
| User entered '1' | System | 09 Nov 2020 02:06:41 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:38:11

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-08T19:06:33', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '6a20d345-b92d-4c7e-b7fb-81e65d326fae' User entered '0' | System | 09 Nov 2020 02:06:41 |
| | System | 09 Nov 2020 02:06:41 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-08T19:06:38', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '6a20d345-b92d-4c7e-b7fb-81e65d326fae' User entered '08 Nov 2020 19:06' | System | 09 Nov 2020 02:06:41 |
| | System | 09 Nov 2020 02:06:41 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '08 Nov 2020 12:00' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '09 Nov 2020 11:59' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 08 Nov 2020 05:27:53 |
| User entered 'Day 8' | System | 08 Nov 2020 05:27:53 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:38:11

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-10T06:34:41', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '83109e77-db57-40d2-9810-a145172beaac' User entered 'Yes (Y)' | System | 10 Nov 2020 13:35:02 |
| | System | 10 Nov 2020 13:35:02 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:38:11

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-10T06:34:45', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '83109e77-db57-40d2-9810-a145172beaac' User entered '99.4' | System | 10 Nov 2020 13:35:02 |
| | System | 10 Nov 2020 13:35:02 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:38:11

Was any MEDICATION TAKEN today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-10T06:34:52', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '83109e77-db57-40d2-9810-a145172beaac' | System | 10 Nov 2020 13:35:02 |
| User entered 'Yes (Y)' | System | 10 Nov 2020 13:35:02 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| 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 'patient confirmed what was taken' (Site from System). | (b) (4), (b) (6) | 23 Nov 2020 14:00:43 |
| 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). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-10T06:34:55', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '83109e77-db57-40d2-9810-a145172beaac' User entered '1' | maggie Tono (b) (4) (b) (4) | 16 Nov 2020 22:19:19 |
| 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 Nov 2020 13:35:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-10T06:34:55', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '83109e77-db57-40d2-9810-a145172beaac' User entered '1' | System | 10 Nov 2020 13:35:02 |
| User entered '1' | System | 10 Nov 2020 13:35:02 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:38:11

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-10T06:34:55', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '83109e77-db57-40d2-9810-a145172beaac' User entered '0' | System | 10 Nov 2020 13:35:02 |
| | System | 10 Nov 2020 13:35:02 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-10T06:34:59', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '83109e77-db57-40d2-9810-a145172beaac' User entered '10 Nov 2020 06:34' | System | 10 Nov 2020 13:35:02 |
| | System | 10 Nov 2020 13:35:02 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '09 Nov 2020 12:00' | System | 08 Nov 2020 05:27:53 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '10 Nov 2020 11:59' | System | 08 Nov 2020 05:27:53 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 09 Nov 2020 02:06:41 |
| User entered 'Day 9' | System | 09 Nov 2020 02:06:41 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:38:11

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-11T08:42:54', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '0ca5fc09-e2b4-475e-9e09-407c7748e2b4' User entered 'No (N)' | System | 11 Nov 2020 15:43:08 |
| | System | 11 Nov 2020 15:43:08 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:38:11

Was any MEDICATION TAKEN today for pain or fever?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-11T08:42:58', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '0ca5fc09-e2b4-475e-9e09-407c7748e2b4' User entered 'Yes (Y)' | System | 11 Nov 2020 15:43:08 |
| | System | 11 Nov 2020 15:43:08 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| 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). | | 23 Nov 2020 14:01:42 |
| 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 'patient confirmed what was taken' (Site from System). | maggie Tono (b) (4) (b) (4) | 16 Nov 2020 22:19:26 |
| 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 | 11 Nov 2020 15:43:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-11T08:43:02', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '0ca5fc09-e2b4-475e-9e09-407c7748e2b4' | System | 11 Nov 2020 15:43:08 |
| User entered '1' | System | 11 Nov 2020 15:43:08 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:38:11

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-11T08:43:02', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '0ca5fc09-e2b4-475e-9e09-407c7748e2b4' User entered '0' | System | 11 Nov 2020 15:43:08 |
| | System | 11 Nov 2020 15:43:08 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-11T08:43:04', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '0ca5fc09-e2b4-475e-9e09-407c7748e2b4' User entered '11 Nov 2020 08:43' | System | 11 Nov 2020 15:43:08 |
| | System | 11 Nov 2020 15:43:08 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '10 Nov 2020 12:00' | System | 09 Nov 2020 02:06:41 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '11 Nov 2020 11:59' | System | 09 Nov 2020 02:06:41 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 10 Nov 2020 13:35:02 |
| User entered 'Day 10' | System | 10 Nov 2020 13:35:02 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 15:38:11

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-11T21:03:13', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '061e7e99-afe5-405d-bf61-c418e70ee7df' User entered 'Yes (Y)' | System | 12 Nov 2020 04:03:40 |
| | System | 12 Nov 2020 04:03:40 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 15:38:11

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-11T21:03:26', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '061e7e99-afe5-405d-bf61-c418e70ee7df' User entered '97.5' | System | 12 Nov 2020 04:03:40 |
| | System | 12 Nov 2020 04:03:40 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-11T21:03:30', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '061e7e99-afe5-405d-bf61-c418e70ee7df' User entered 'Yes (Y)' | System | 12 Nov 2020 04:03:40 |
| | System | 12 Nov 2020 04:03:40 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| 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 'patient confirmed what was taken' (Site from System). | (b) (4), (b) (6) | 23 Nov 2020 14:01:47 |
| 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). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-11T21:03:34', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '061e7e99-afe5-405d-bf61-c418e70ee7df' User entered '1' | maggie Tono (b) (4) (b) (4) | 16 Nov 2020 22:19:35 |
| | System | 12 Nov 2020 04:03:40 |
| | System | 12 Nov 2020 04:03:40 |
| | System | 12 Nov 2020 04:03:40 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 15:38:11

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-11T21:03:34', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '061e7e99-afe5-405d-bf61-c418e70ee7df' User entered '0' | System | 12 Nov 2020 04:03:40 |
| | System | 12 Nov 2020 04:03:40 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-11T21:03:36', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '061e7e99-afe5-405d-bf61-c418e70ee7df' User entered '11 Nov 2020 21:03' | System | 12 Nov 2020 04:03:40 |
| | System | 12 Nov 2020 04:03:40 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '11 Nov 2020 12:00' | System | 10 Nov 2020 13:35:02 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '12 Nov 2020 11:59' | System | 10 Nov 2020 13:35:02 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 12 Nov 2020 04:03:40 |
| User entered 'Day 11' | System | 12 Nov 2020 04:03:40 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 15:38:11

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-12T21:53:10', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'cbea7ba9-9fee-4852-8d05-eb1d9ac15e61' User entered 'Yes (Y)' | System | 13 Nov 2020 04:53:28 |
| | System | 13 Nov 2020 04:53:28 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 15:38:11

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-12T21:53:14', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'cbea7ba9-9fee-4852-8d05-eb1d9ac15e61' User entered '98.5' | System | 13 Nov 2020 04:53:28 |
| | System | 13 Nov 2020 04:53:28 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 15:38:11

Was any MEDICATION TAKEN today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-12T21:53:23', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'cbea7ba9-9fee-4852-8d05-eb1d9ac15e61' | System | 13 Nov 2020 04:53:28 |
| User entered 'No (N)' | System | 13 Nov 2020 04:53:28 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-12T21:53:26', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'cbea7ba9-9fee-4852-8d05-eb1d9ac15e61' User entered '12 Nov 2020 21:53' | System | 13 Nov 2020 04:53:28 |
| | System | 13 Nov 2020 04:53:28 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '12 Nov 2020 12:00' | System | 12 Nov 2020 04:03:40 |

US3192734

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '13 Nov 2020 11:59' | System | 12 Nov 2020 04:03:40 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 02 Nov 2020 19:44:32 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-02T13:03:55', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '173bd67b-f08a-4397-9c47-88e4b193b53a' User entered 'None (1)' | System | 02 Nov 2020 20:04:20 |
| | System | 02 Nov 2020 20:04:20 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-02T13:04:02', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '173bd67b-f08a-4397-9c47-88e4b193b53a' User entered 'No (N)' | System | 02 Nov 2020 20:04:20 |
| | System | 02 Nov 2020 20:04:20 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-02T13:04:04', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '173bd67b-f08a-4397-9c47-88e4b193b53a' User entered 'No (N)' | System | 02 Nov 2020 20:04:20 |
| | System | 02 Nov 2020 20:04:20 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-02T13:04:10', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '173bd67b-f08a-4397-9c47-88e4b193b53a' User entered 'None (1)' | System | 02 Nov 2020 20:04:20 |
| | System | 02 Nov 2020 20:04:20 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-02T13:04:15', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '173bd67b-f08a-4397-9c47-88e4b193b53a' User entered '02 Nov 2020 13:04' | System | 02 Nov 2020 20:04:20 |
| | System | 02 Nov 2020 20:04:20 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '02 Nov 2020 12:57' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '02 Nov 2020 15:27' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 02 Nov 2020 19:44:32 |
| User entered 'Day 1, after vaccination (at home)' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-02T20:42:10', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'b500f15e-bd99-4f41-914f-a3739552f747' | System | 03 Nov 2020 03:42:43 |
| User entered 'None (1)' | System | 03 Nov 2020 03:42:43 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-02T20:42:20', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'b500f15e-bd99-4f41-914f-a3739552f747' | System | 03 Nov 2020 03:42:43 |
| User entered 'No (N)' | System | 03 Nov 2020 03:42:43 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-02T20:42:23', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'b500f15e-bd99-4f41-914f-a3739552f747' | System | 03 Nov 2020 03:42:43 |
| User entered 'No (N)' | System | 03 Nov 2020 03:42:43 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-02T20:42:28', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'b500f15e-bd99-4f41-914f-a3739552f747' | System | 03 Nov 2020 03:42:43 |
| User entered 'None (1)' | System | 03 Nov 2020 03:42:43 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-02T20:42:39', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'b500f15e-bd99-4f41-914f-a3739552f747' | System | 03 Nov 2020 03:42:43 |
| User entered '02 Nov 2020 20:42' | System | 03 Nov 2020 03:42:43 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '02 Nov 2020 16:22' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '03 Nov 2020 11:59' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 02 Nov 2020 19:44:32 |
| User entered 'Day 2' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-04T07:05:09', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'd5e989aa-430e-4e60-b3f3-22c3b06c463b' User entered 'None (1)' | System | 04 Nov 2020 15:05:43 |
| | System | 04 Nov 2020 15:05:43 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-04T07:05:16', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'd5e989aa-430e-4e60-b3f3-22c3b06c463b' User entered 'No (N)' | System | 04 Nov 2020 15:05:43 |
| | System | 04 Nov 2020 15:05:43 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-04T07:05:28', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'd5e989aa-430e-4e60-b3f3-22c3b06c463b' User entered 'No (N)' | System | 04 Nov 2020 15:05:43 |
| | System | 04 Nov 2020 15:05:43 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-04T07:05:34', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'd5e989aa-430e-4e60-b3f3-22c3b06c463b' User entered 'None (1)' | System | 04 Nov 2020 15:05:43 |
| | System | 04 Nov 2020 15:05:43 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-04T07:05:39', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'd5e989aa-430e-4e60-b3f3-22c3b06c463b' User entered '04 Nov 2020 07:05' | System | 04 Nov 2020 15:05:43 |
| | System | 04 Nov 2020 15:05:43 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '03 Nov 2020 12:00' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '04 Nov 2020 11:59' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 02 Nov 2020 19:44:32 |
| User entered 'Day 3' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-05T04:17:40', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'f4b9e7b1-2e98-49a4-bc26-3ee711dc6e93' User entered 'None (1)' | System | 05 Nov 2020 12:17:52 |
| | System | 05 Nov 2020 12:17:52 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-05T04:17:42', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'f4b9e7b1-2e98-49a4-bc26-3ee711dc6e93' | System | 05 Nov 2020 12:17:52 |
| User entered 'No (N)' | System | 05 Nov 2020 12:17:52 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-05T04:17:44', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'f4b9e7b1-2e98-49a4-bc26-3ee711dc6e93' | System | 05 Nov 2020 12:17:52 |
| User entered 'No (N)' | System | 05 Nov 2020 12:17:52 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-05T04:17:47', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'f4b9e7b1-2e98-49a4-bc26-3ee711dc6e93' | System | 05 Nov 2020 12:17:52 |
| User entered 'None (1)' | System | 05 Nov 2020 12:17:52 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-05T04:17:50', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'f4b9e7b1-2e98-49a4-bc26-3ee711dc6e93' User entered '05 Nov 2020 04:17' | System | 05 Nov 2020 12:17:52 |
| | System | 05 Nov 2020 12:17:52 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '04 Nov 2020 12:00' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '05 Nov 2020 11:59' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 02 Nov 2020 19:44:32 |
| User entered 'Day 4' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-05T18:11:32', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '24a7a131-c84a-4060-9d92-7a5069524521' | System | 06 Nov 2020 02:11:53 |
| User entered 'None (1)' | System | 06 Nov 2020 02:11:53 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-05T18:11:34', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '24a7a131-c84a-4060-9d92-7a5069524521' User entered 'No (N)' | System | 06 Nov 2020 02:11:53 |
| | System | 06 Nov 2020 02:11:53 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-05T18:11:37', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '24a7a131-c84a-4060-9d92-7a5069524521' User entered 'No (N)' | System | 06 Nov 2020 02:11:53 |
| | System | 06 Nov 2020 02:11:53 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-05T18:11:44', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '24a7a131-c84a-4060-9d92-7a5069524521' User entered 'None (1)' | System | 06 Nov 2020 02:11:53 |
| | System | 06 Nov 2020 02:11:53 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-05T18:11:49', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '24a7a131-c84a-4060-9d92-7a5069524521' User entered '05 Nov 2020 18:11' | System | 06 Nov 2020 02:11:53 |
| | System | 06 Nov 2020 02:11:53 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '05 Nov 2020 12:00' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '06 Nov 2020 11:59' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 02 Nov 2020 19:44:32 |
| User entered 'Day 5' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-07T07:08:48', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '5035415d-e8ac-4cf3-90c5-b9c40a46c0d1' User entered 'None (1)' | System | 07 Nov 2020 15:09:04 |
| | System | 07 Nov 2020 15:09:04 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-07T07:08:51', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '5035415d-e8ac-4cf3-90c5-b9c40a46c0d1' User entered 'No (N)' | System | 07 Nov 2020 15:09:04 |
| | System | 07 Nov 2020 15:09:04 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-07T07:08:55', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '5035415d-e8ac-4cf3-90c5-b9c40a46c0d1' User entered 'No (N)' | System | 07 Nov 2020 15:09:04 |
| | System | 07 Nov 2020 15:09:04 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-07T07:08:58', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '5035415d-e8ac-4cf3-90c5-b9c40a46c0d1' User entered 'None (1)' | System | 07 Nov 2020 15:09:04 |
| | System | 07 Nov 2020 15:09:04 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-07T07:09:02', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '5035415d-e8ac-4cf3-90c5-b9c40a46c0d1' User entered '07 Nov 2020 07:09' | System | 07 Nov 2020 15:09:04 |
| | System | 07 Nov 2020 15:09:04 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '06 Nov 2020 12:00' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '07 Nov 2020 11:59' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 02 Nov 2020 19:44:32 |
| User entered 'Day 6' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-07T22:27:53', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '75ce87ee-dd1e-4841-98c1-133923e5315d' User entered 'None (1)' | System | 08 Nov 2020 05:28:11 |
| | System | 08 Nov 2020 05:28:11 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-07T22:27:56', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '75ce87ee-dd1e-4841-98c1-133923e5315d' User entered 'No (N)' | System | 08 Nov 2020 05:28:11 |
| | System | 08 Nov 2020 05:28:11 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-07T22:28:02', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '75ce87ee-dd1e-4841-98c1-133923e5315d' User entered 'No (N)' | System | 08 Nov 2020 05:28:11 |
| | System | 08 Nov 2020 05:28:11 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-07T22:28:04', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '75ce87ee-dd1e-4841-98c1-133923e5315d' User entered 'None (1)' | System | 08 Nov 2020 05:28:11 |
| | System | 08 Nov 2020 05:28:11 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-07T22:28:08', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '75ce87ee-dd1e-4841-98c1-133923e5315d' User entered '07 Nov 2020 22:28' | System | 08 Nov 2020 05:28:11 |
| | System | 08 Nov 2020 05:28:11 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '07 Nov 2020 12:00' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '08 Nov 2020 11:59' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 02 Nov 2020 19:44:32 |
| User entered 'Day 7' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-08T19:06:42', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'a9361fa7-d8a2-4def-b9c7-f3b18d261e23' | System | 09 Nov 2020 02:06:56 |
| User entered 'None (1)' | System | 09 Nov 2020 02:06:56 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-08T19:06:45', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'a9361fa7-d8a2-4def-b9c7-f3b18d261e23' | System | 09 Nov 2020 02:06:56 |
| User entered 'No (N)' | System | 09 Nov 2020 02:06:56 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-08T19:06:47', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'a9361fa7-d8a2-4def-b9c7-f3b18d261e23' | System | 09 Nov 2020 02:06:56 |
| User entered 'No (N)' | System | 09 Nov 2020 02:06:56 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-08T19:06:50', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'a9361fa7-d8a2-4def-b9c7-f3b18d261e23' | System | 09 Nov 2020 02:06:56 |
| User entered 'None (1)' | System | 09 Nov 2020 02:06:56 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-08T19:06:54', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'a9361fa7-d8a2-4def-b9c7-f3b18d261e23' | System | 09 Nov 2020 02:06:56 |
| User entered '08 Nov 2020 19:06' | System | 09 Nov 2020 02:06:56 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '08 Nov 2020 12:00' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '09 Nov 2020 11:59' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 02 Nov 2020 19:44:32 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-02T13:04:27', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '253eaad1-27a0-4346-a089-72fc9e53a07a' User entered 'None (0)' | System | 02 Nov 2020 20:04:51 |
| | System | 02 Nov 2020 20:04:51 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-02T13:04:29', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '253eaad1-27a0-4346-a089-72fc9e53a07a' User entered 'None (0)' | System | 02 Nov 2020 20:04:51 |
| | System | 02 Nov 2020 20:04:51 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-02T13:04:31', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '253eaad1-27a0-4346-a089-72fc9e53a07a' User entered 'None (0)' | System | 02 Nov 2020 20:04:51 |
| | System | 02 Nov 2020 20:04:51 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-02T13:04:33', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '253eaad1-27a0-4346-a089-72fc9e53a07a' User entered 'None (0)' | System | 02 Nov 2020 20:04:51 |
| | System | 02 Nov 2020 20:04:51 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-02T13:04:35', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '253eaad1-27a0-4346-a089-72fc9e53a07a' User entered 'None (0)' | System | 02 Nov 2020 20:04:51 |
| | System | 02 Nov 2020 20:04:51 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-02T13:04:37', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '253eaad1-27a0-4346-a089-72fc9e53a07a' User entered 'None (0)' | System | 02 Nov 2020 20:04:51 |
| | System | 02 Nov 2020 20:04:51 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-02T13:04:42', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '253eaad1-27a0-4346-a089-72fc9e53a07a' User entered 'No (N)' | System | 02 Nov 2020 20:04:51 |
| | System | 02 Nov 2020 20:04:51 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-02T13:04:48', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '253ead1-27a0-4346-a089-72fc9e53a07a' User entered '02 Nov 2020 13:04' | System | 02 Nov 2020 20:04:51 |
| | System | 02 Nov 2020 20:04:51 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '02 Nov 2020 12:57' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '02 Nov 2020 15:27' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 02 Nov 2020 19:44:32 |
| User entered 'Day 1, after vaccination (at home)' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-02T20:42:44', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '0679484d-50d0-4567-aab3-9d283c0e9c78' User entered 'None (0)' | System | 03 Nov 2020 03:43:09 |
| | System | 03 Nov 2020 03:43:09 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-02T20:42:47', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '0679484d-50d0-4567-aab3-9d283c0e9c78' User entered 'None (0)' | System | 03 Nov 2020 03:43:09 |
| | System | 03 Nov 2020 03:43:09 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-02T20:42:51', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '0679484d-50d0-4567-aab3-9d283c0e9c78' User entered 'None (0)' | System | 03 Nov 2020 03:43:09 |
| | System | 03 Nov 2020 03:43:09 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-02T20:42:53', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '0679484d-50d0-4567-aab3-9d283c0e9c78' User entered 'None (0)' | System | 03 Nov 2020 03:43:09 |
| | System | 03 Nov 2020 03:43:09 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-02T20:42:55', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '0679484d-50d0-4567-aab3-9d283c0e9c78' User entered 'None (0)' | System | 03 Nov 2020 03:43:09 |
| | System | 03 Nov 2020 03:43:09 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-02T20:42:57', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '0679484d-50d0-4567-aab3-9d283c0e9c78' User entered 'None (0)' | System | 03 Nov 2020 03:43:09 |
| | System | 03 Nov 2020 03:43:09 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-02T20:42:59', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '0679484d-50d0-4567-aab3-9d283c0e9c78' User entered 'No (N)' | System | 03 Nov 2020 03:43:09 |
| | System | 03 Nov 2020 03:43:09 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-02T20:43:06', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '0679484d-50d0-4567-aab3-9d283c0e9c78' User entered '02 Nov 2020 20:43' | System | 03 Nov 2020 03:43:09 |
| | System | 03 Nov 2020 03:43:09 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '02 Nov 2020 16:22' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '03 Nov 2020 11:59' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 02 Nov 2020 19:44:32 |
| User entered 'Day 2' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:11

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-04T07:05:45', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '0dd1e42b-c408-47b1-932a-3310b79048be' User entered 'None (0)' | System | 04 Nov 2020 15:06:35 |
| | System | 04 Nov 2020 15:06:35 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:11

FATIGUE

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-04T07:06:10', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '0dd1e42b-c408-47b1-932a-3310b79048be' User entered 'Some interference with activity (2)' | System | 04 Nov 2020 15:06:35 |
| | System | 04 Nov 2020 15:06:35 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:11

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-04T07:06:14', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '0dd1e42b-c408-47b1-932a-3310b79048be' User entered 'None (0)' | System | 04 Nov 2020 15:06:35 |
| | System | 04 Nov 2020 15:06:35 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:11

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-04T07:06:17', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '0dd1e42b-c408-47b1-932a-3310b79048be' User entered 'None (0)' | System | 04 Nov 2020 15:06:35 |
| | System | 04 Nov 2020 15:06:35 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:11

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-04T07:06:20', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '0dd1e42b-c408-47b1-932a-3310b79048be' User entered 'None (0)' | System | 04 Nov 2020 15:06:35 |
| | System | 04 Nov 2020 15:06:35 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:11

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-04T07:06:23', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '0dd1e42b-c408-47b1-932a-3310b79048be' User entered 'None (0)' | System | 04 Nov 2020 15:06:35 |
| | System | 04 Nov 2020 15:06:35 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-04T07:06:27', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '0dd1e42b-c408-47b1-932a-3310b79048be' User entered 'No (N)' | System | 04 Nov 2020 15:06:35 |
| | System | 04 Nov 2020 15:06:35 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-04T07:06:32', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '0dd1e42b-c408-47b1-932a-3310b79048be' User entered '04 Nov 2020 07:06' | System | 04 Nov 2020 15:06:35 |
| | System | 04 Nov 2020 15:06:35 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '03 Nov 2020 12:00' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '04 Nov 2020 11:59' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 02 Nov 2020 19:44:32 |
| User entered 'Day 3' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:11

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-05T04:17:55', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '5e8ce6db-bbc0-4823-af97-99ee35c7239d' User entered 'None (0)' | System | 05 Nov 2020 12:18:21 |
| | System | 05 Nov 2020 12:18:21 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:11

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-05T04:18:01', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '5e8ce6db-bbc0-4823-af97-99ee35c7239d' User entered 'None (0)' | System | 05 Nov 2020 12:18:21 |
| | System | 05 Nov 2020 12:18:21 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:11

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-05T04:18:03', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '5e8ce6db-bbc0-4823-af97-99ee35c7239d' User entered 'None (0)' | System | 05 Nov 2020 12:18:21 |
| | System | 05 Nov 2020 12:18:21 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:11

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-05T04:18:06', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '5e8ce6db-bbc0-4823-af97-99ee35c7239d' User entered 'None (0)' | System | 05 Nov 2020 12:18:21 |
| | System | 05 Nov 2020 12:18:21 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:11

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-05T04:18:08', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '5e8ce6db-bbc0-4823-af97-99ee35c7239d' User entered 'None (0)' | System | 05 Nov 2020 12:18:21 |
| | System | 05 Nov 2020 12:18:21 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:11

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-05T04:18:10', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '5e8ce6db-bbc0-4823-af97-99ee35c7239d' User entered 'None (0)' | System | 05 Nov 2020 12:18:21 |
| | System | 05 Nov 2020 12:18:21 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-05T04:18:13', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '5e8ce6db-bbc0-4823-af97-99ee35c7239d' User entered 'No (N)' | System | 05 Nov 2020 12:18:21 |
| | System | 05 Nov 2020 12:18:21 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-05T04:18:18', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '5e8ce6db-bbc0-4823-af97-99ee35c7239d' User entered '05 Nov 2020 04:18' | System | 05 Nov 2020 12:18:21 |
| | System | 05 Nov 2020 12:18:21 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '04 Nov 2020 12:00' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '05 Nov 2020 11:59' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 02 Nov 2020 19:44:32 |
| User entered 'Day 4' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:11

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-05T18:12:05', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '0006ca3e-597e-424e-bc5c-b187892224be' | System | 06 Nov 2020 02:12:56 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)' | System | 06 Nov 2020 02:12:56 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:11

FATIGUE

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-05T18:12:13', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '0006ca3e-597e-424e-bc5c-b187892224be' User entered 'Some interference with activity (2)' | System | 06 Nov 2020 02:12:56 |
| | System | 06 Nov 2020 02:12:56 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:11

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-05T18:12:20', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '0006ca3e-597e-424e-bc5c-b187892224be' User entered 'Significant; prevents daily activity (3)' | System | 06 Nov 2020 02:12:56 |
| | System | 06 Nov 2020 02:12:56 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:11

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-05T18:12:25', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '0006ca3e-597e-424e-bc5c-b187892224be' User entered 'Significant; prevents daily activity (3)' | System | 06 Nov 2020 02:12:56 |
| | System | 06 Nov 2020 02:12:56 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:11

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-05T18:12:28', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '0006ca3e-597e-424e-bc5c-b187892224be' User entered 'None (0)' | System | 06 Nov 2020 02:12:56 |
| | System | 06 Nov 2020 02:12:56 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:11

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-05T18:12:38', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '0006ca3e-597e-424e-bc5c-b187892224be' | System | 06 Nov 2020 02:12:56 |
| User entered 'Some interference with activity not requiring medical attention (2)' | System | 06 Nov 2020 02:12:56 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-05T18:12:43', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '0006ca3e-597e-424e-bc5c-b187892224be' User entered 'No (N)' | System | 06 Nov 2020 02:12:56 |
| | System | 06 Nov 2020 02:12:56 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-05T18:12:51', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '0006ca3e-597e-424e-bc5c-b187892224be' User entered '05 Nov 2020 18:12' | System | 06 Nov 2020 02:12:56 |
| | System | 06 Nov 2020 02:12:56 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '05 Nov 2020 12:00' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '06 Nov 2020 11:59' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 02 Nov 2020 19:44:32 |
| User entered 'Day 5' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:11

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-07T07:09:21', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '5a418218-b14e-48f4-a0e0-1e0a8517c818' | System | 07 Nov 2020 15:09:58 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)' | System | 07 Nov 2020 15:09:58 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:11

FATIGUE

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-07T07:09:26', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '5a418218-b14e-48f4-a0e0-1e0a8517c818' User entered 'Some interference with activity (2)' | System | 07 Nov 2020 15:09:58 |
| | System | 07 Nov 2020 15:09:58 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:11

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-07T07:09:32', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '5a418218-b14e-48f4-a0e0-1e0a8517c818' User entered 'Significant; prevents daily activity (3)' | System | 07 Nov 2020 15:09:58 |
| | System | 07 Nov 2020 15:09:58 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:11

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-07T07:09:38', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '5a418218-b14e-48f4-a0e0-1e0a8517c818' User entered 'Significant; prevents daily activity (3)' | System | 07 Nov 2020 15:09:58 |
| | System | 07 Nov 2020 15:09:58 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:11

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-07T07:09:41', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '5a418218-b14e-48f4-a0e0-1e0a8517c818' User entered 'None (0)' | System | 07 Nov 2020 15:09:58 |
| | System | 07 Nov 2020 15:09:58 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:11

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-07T07:09:47', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '5a418218-b14e-48f4-a0e0-1e0a8517c818' | System | 07 Nov 2020 15:09:58 |
| User entered 'Some interference with activity not requiring medical attention (2)' | System | 07 Nov 2020 15:09:58 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-07T07:09:51', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '5a418218-b14e-48f4-a0e0-1e0a8517c818' User entered 'No (N)' | System | 07 Nov 2020 15:09:58 |
| | System | 07 Nov 2020 15:09:58 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-07T07:09:57', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '5a418218-b14e-48f4-a0e0-1e0a8517c818' User entered '07 Nov 2020 07:09' | System | 07 Nov 2020 15:09:58 |
| | System | 07 Nov 2020 15:09:58 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '06 Nov 2020 12:00' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '07 Nov 2020 11:59' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 02 Nov 2020 19:44:32 |
| User entered 'Day 6' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:11

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-07T22:28:28', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '651afd32-3c96-477a-bd3b-e89e51a622b0' | System | 08 Nov 2020 05:29:27 |
| User entered 'Any use of prescription pain reliever or System prevents daily activity (3)' | | 08 Nov 2020 05:29:27 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:11

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-07T22:28:36', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '651afd32-3c96-477a-bd3b-e89e51a622b0' | System | 08 Nov 2020 05:29:27 |
| User entered 'Some interference with activity (2)' | System | 08 Nov 2020 05:29:27 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:11

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-07T22:28:45', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '651afd32-3c96-477a-bd3b-e89e51a622b0' User entered 'Significant; prevents daily activity (3)' | System | 08 Nov 2020 05:29:27 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:11

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-07T22:28:50', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '651afd32-3c96-477a-bd3b-e89e51a622b0' User entered 'Some interference with activity (2)' | System | 08 Nov 2020 05:29:27 |
| | System | 08 Nov 2020 05:29:27 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:11

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-07T22:28:58', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '651afd32-3c96-477a-bd3b-e89e51a622b0' | System | 08 Nov 2020 05:29:27 |
| User entered 'No interference with activity or 1-2 episodes/24 hours (1)' | System | 08 Nov 2020 05:29:27 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:11

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-07T22:29:05', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '651afd32-3c96-477a-bd3b-e89e51a622b0' | System | 08 Nov 2020 05:29:27 |
| User entered 'No interference with activity (1)' | System | 08 Nov 2020 05:29:27 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-07T22:29:08', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '651afd32-3c96-477a-bd3b-e89e51a622b0' User entered 'No (N)' | System | 08 Nov 2020 05:29:27 |
| | System | 08 Nov 2020 05:29:27 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-07T22:29:21', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '651afd32-3c96-477a-bd3b-e89e51a622b0' User entered '07 Nov 2020 22:29' | System | 08 Nov 2020 05:29:27 |
| | System | 08 Nov 2020 05:29:27 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '07 Nov 2020 12:00' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '08 Nov 2020 11:59' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 02 Nov 2020 19:44:32 |
| User entered 'Day 7' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:11

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-08T19:07:04', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '15575c29-738e-4d8d-a256-2c4cf37c5efa' | System | 09 Nov 2020 02:07:53 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)' | System | 09 Nov 2020 02:07:53 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:11

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-08T19:07:15', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '15575c29-738e-4d8d-a256-2c4cf37c5efa' User entered 'Significant; prevents daily activity (3)' | System | 09 Nov 2020 02:07:53 |
| | System | 09 Nov 2020 02:07:53 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:11

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-08T19:07:21', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '15575c29-738e-4d8d-a256-2c4cf37c5efa' User entered 'Significant; prevents daily activity (3)' | System | 09 Nov 2020 02:07:53 |
| | System | 09 Nov 2020 02:07:53 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:11

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-08T19:07:25', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '15575c29-738e-4d8d-a256-2c4cf37c5efa' User entered 'Significant; prevents daily activity (3)' | System | 09 Nov 2020 02:07:53 |
| | System | 09 Nov 2020 02:07:53 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:11

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-08T19:07:28', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '15575c29-738e-4d8d-a256-2c4cf37c5efa' User entered 'None (0)' | System | 09 Nov 2020 02:07:53 |
| | System | 09 Nov 2020 02:07:53 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:11

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-08T19:07:31', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '15575c29-738e-4d8d-a256-2c4cf37c5efa' User entered 'None (0)' | System | 09 Nov 2020 02:07:53 |
| | System | 09 Nov 2020 02:07:53 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-08T19:07:34', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '15575c29-738e-4d8d-a256-2c4cf37c5efa' User entered 'No (N)' | System | 09 Nov 2020 02:07:53 |
| | System | 09 Nov 2020 02:07:53 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-08T19:07:49', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '15575c29-738e-4d8d-a256-2c4cf37c5efa' User entered '08 Nov 2020 19:07' | System | 09 Nov 2020 02:07:53 |
| | System | 09 Nov 2020 02:07:53 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '08 Nov 2020 12:00' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '09 Nov 2020 11:59' | System | 02 Nov 2020 19:44:32 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 08 Nov 2020 05:29:27 |
| User entered 'Day 8' | System | 08 Nov 2020 05:29:27 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:38:11

Select one response below to indicate the intensity of your **HEADACHE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-10T06:35:07', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '3ea556d8-eec1-4357-b0e5-237b665be196' | System | 10 Nov 2020 13:35:16 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)' | System | 10 Nov 2020 13:35:16 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-10T06:35:12', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '3ea556d8-eec1-4357-b0e5-237b665be196' User entered '10 Nov 2020 06:35' | System | 10 Nov 2020 13:35:16 |
| | System | 10 Nov 2020 13:35:16 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '09 Nov 2020 12:00' | System | 08 Nov 2020 05:29:27 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '10 Nov 2020 11:59' | System | 08 Nov 2020 05:29:27 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 09 Nov 2020 02:07:53 |
| User entered 'Day 9' | System | 09 Nov 2020 02:07:53 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:38:11

Select one response below to indicate the intensity of your **HEADACHE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-11T08:43:09', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'de4b598e-40e4-4562-9f3a-6fc0eb8a9126' | System | 11 Nov 2020 15:43:15 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)' | System | 11 Nov 2020 15:43:15 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-11T08:43:11', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'de4b598e-40e4-4562-9f3a-6fc0eb8a9126' User entered '11 Nov 2020 08:43' | System | 11 Nov 2020 15:43:15 |
| | System | 11 Nov 2020 15:43:15 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '10 Nov 2020 12:00' | System | 09 Nov 2020 02:07:53 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '11 Nov 2020 11:59' | System | 09 Nov 2020 02:07:53 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 10 Nov 2020 13:35:16 |
| User entered 'Day 10' | System | 10 Nov 2020 13:35:16 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 15:38:11

Select one response below to indicate the intensity of your **HEADACHE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-11T21:03:42', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '134b6aa2-f001-4c17-8249-eefefb95d213' | System | 12 Nov 2020 04:03:48 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)' | System | 12 Nov 2020 04:03:48 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-11T21:03:45', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '134b6aa2-f001-4c17-8249-eefefb95d213' User entered '11 Nov 2020 21:03' | System | 12 Nov 2020 04:03:48 |
| | System | 12 Nov 2020 04:03:48 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '11 Nov 2020 12:00' | System | 10 Nov 2020 13:35:16 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '12 Nov 2020 11:59' | System | 10 Nov 2020 13:35:16 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 11 Nov 2020 15:43:15 |
| User entered 'Day 11' | System | 11 Nov 2020 15:43:15 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 15:38:11

Select one response below to indicate the intensity of your **HEADACHE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-12T21:53:33', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'd5c43513-63fe-46a8-b10e-a41ecf3a2a27' | System | 13 Nov 2020 04:53:40 |
| User entered 'No interference with activity (1)' | System | 13 Nov 2020 04:53:40 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-12T21:53:37', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'd5c43513-63fe-46a8-b10e-a41ecf3a2a27' | System | 13 Nov 2020 04:53:40 |
| User entered '12 Nov 2020 21:53' | System | 13 Nov 2020 04:53:40 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '12 Nov 2020 12:00' | System | 11 Nov 2020 15:43:15 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(11)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '13 Nov 2020 11:59' | System | 11 Nov 2020 15:43:15 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(12)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 12 Nov 2020 04:03:48 |
| User entered 'Day 12' | System | 12 Nov 2020 04:03:48 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(12)

Generated On: 09 Jun 2021 15:38:11

Select one response below to indicate the intensity of your **HEADACHE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-13T21:52:41', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '1a574667-fdae-4080-8586-025af7fe1a78' | System | 14 Nov 2020 04:52:48 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)' | System | 14 Nov 2020 04:52:48 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(12)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-13T21:52:44', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '1a574667-fdae-4080-8586-025af7fe1a78' | System | 14 Nov 2020 04:52:48 |
| User entered '13 Nov 2020 21:52' | System | 14 Nov 2020 04:52:48 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(12)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '13 Nov 2020 12:00' | System | 12 Nov 2020 04:03:48 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(12)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '14 Nov 2020 11:59' | System | 12 Nov 2020 04:03:48 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(13)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 13 Nov 2020 04:53:40 |
| User entered 'Day 13' | System | 13 Nov 2020 04:53:40 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(13)

Generated On: 09 Jun 2021 15:38:11

Select one response below to indicate the intensity of your **HEADACHE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-15T07:15:30', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '81181c3f-b337-47db-9185-842f47cad42c' | System | 15 Nov 2020 14:15:35 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)' | System | 15 Nov 2020 14:15:35 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(13)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-15T07:15:33', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '81181c3f-b337-47db-9185-842f47cad42c' User entered '15 Nov 2020 07:15' | System | 15 Nov 2020 14:15:35 |
| | System | 15 Nov 2020 14:15:35 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(13)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '14 Nov 2020 12:00' | System | 13 Nov 2020 04:53:40 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(13)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '15 Nov 2020 11:59' | System | 13 Nov 2020 04:53:40 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(14)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 14 Nov 2020 04:52:48 |
| User entered 'Day 14' | System | 14 Nov 2020 04:52:48 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(14)

Generated On: 09 Jun 2021 15:38:11

Select one response below to indicate the intensity of your **HEADACHE**

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(14)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(14)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '15 Nov 2020 12:00' | System | 14 Nov 2020 04:52:48 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(14)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '16 Nov 2020 11:59' | System | 14 Nov 2020 04:52:48 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(15)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 15 Nov 2020 14:15:35 |
| User entered 'Day 15' | System | 15 Nov 2020 14:15:35 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(15)

Generated On: 09 Jun 2021 15:38:11

Select one response below to indicate the intensity of your **HEADACHE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-16T12:09:21', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '77eb0384-ecff-426a-a185-9b7e00cdabbd' | System | 16 Nov 2020 19:09:29 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)' | System | 16 Nov 2020 19:09:29 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(15)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-16T12:09:24', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '77eb0384-ecff-426a-a185-9b7e00cdabbd' User entered '16 Nov 2020 12:09' | System | 16 Nov 2020 19:09:29 |
| | System | 16 Nov 2020 19:09:29 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(15)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '16 Nov 2020 12:00' | System | 15 Nov 2020 14:15:35 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(15)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '17 Nov 2020 11:59' | System | 15 Nov 2020 14:15:35 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(16)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 16 Nov 2020 19:09:29 |
| User entered 'Day 16' | System | 16 Nov 2020 19:09:29 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(16)

Generated On: 09 Jun 2021 15:38:11

Select one response below to indicate the intensity of your **HEADACHE**

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(16)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(16)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '17 Nov 2020 12:00' | System | 16 Nov 2020 19:09:29 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(16)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '18 Nov 2020 11:59' | System | 16 Nov 2020 19:09:29 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(17)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 16 Nov 2020 19:09:29 |
| User entered 'Day 17' | System | 16 Nov 2020 19:09:29 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(17)

Generated On: 09 Jun 2021 15:38:11

Select one response below to indicate the intensity of your **HEADACHE**

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(17)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(17)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '18 Nov 2020 12:00' | System | 16 Nov 2020 19:09:29 |

US3192734

Folder: Diary Dose 2 (1)

Form: Headache_Day(17)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '19 Nov 2020 11:59' | System | 16 Nov 2020 19:09:29 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 08 Nov 2020 05:29:27 |
| User entered 'Day 8' | System | 08 Nov 2020 05:29:27 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-10T06:35:21', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '9425d312-dc07-4b6c-b1af-e5eb842e1762' | System | 10 Nov 2020 13:35:27 |
| User entered 'Significant; prevents daily activity (3)' | System | 10 Nov 2020 13:35:27 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-10T06:35:24', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '9425d312-dc07-4b6c-b1af-e5eb842e1762' User entered '10 Nov 2020 06:35' | System | 10 Nov 2020 13:35:27 |
| | System | 10 Nov 2020 13:35:27 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '09 Nov 2020 12:00' | System | 08 Nov 2020 05:29:27 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '10 Nov 2020 11:59' | System | 08 Nov 2020 05:29:27 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 09 Nov 2020 02:07:53 |
| User entered 'Day 9' | System | 09 Nov 2020 02:07:53 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-11T08:43:16', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'f10eab0c-d7d7-4e37-98a9-065dcea2fba9' User entered 'Significant; prevents daily activity (3)' | System | 11 Nov 2020 15:43:22 |
| | System | 11 Nov 2020 15:43:22 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-11T08:43:18', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'f10eab0c-d7d7-4e37-98a9-065dcea2fba9' User entered '11 Nov 2020 08:43' | System | 11 Nov 2020 15:43:22 |
| | System | 11 Nov 2020 15:43:22 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '10 Nov 2020 12:00' | System | 09 Nov 2020 02:07:53 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '11 Nov 2020 11:59' | System | 09 Nov 2020 02:07:53 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 10 Nov 2020 13:35:27 |
| User entered 'Day 10' | System | 10 Nov 2020 13:35:27 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-11T21:03:50', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '033b4f96-030f-4824-82c6-b77cd73a182a' User entered 'Significant; prevents daily activity (3)' | System | 12 Nov 2020 04:03:55 |
| | System | 12 Nov 2020 04:03:55 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-11T21:03:53', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '033b4f96-030f-4824-82c6-b77cd73a182a' User entered '11 Nov 2020 21:03' | System | 12 Nov 2020 04:03:55 |
| | System | 12 Nov 2020 04:03:55 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '11 Nov 2020 12:00' | System | 10 Nov 2020 13:35:27 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '12 Nov 2020 11:59' | System | 10 Nov 2020 13:35:27 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 11 Nov 2020 15:43:22 |
| User entered 'Day 11' | System | 11 Nov 2020 15:43:22 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-12T21:53:41', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'b9b9496b-a6e9-41d2-a0c1-1f35e30146b9' User entered 'Some interference with activity (2)' | System | 13 Nov 2020 04:53:47 |
| | System | 13 Nov 2020 04:53:47 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-12T21:53:44', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'b9b9496b-a6e9-41d2-a0c1-1f35e30146b9' User entered '12 Nov 2020 21:53' | System | 13 Nov 2020 04:53:47 |
| | System | 13 Nov 2020 04:53:47 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '12 Nov 2020 12:00' | System | 11 Nov 2020 15:43:22 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '13 Nov 2020 11:59' | System | 11 Nov 2020 15:43:22 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 12 Nov 2020 04:03:55 |
| User entered 'Day 12' | System | 12 Nov 2020 04:03:55 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-13T21:52:49', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '165a896d-05a2-4ebe-995f-54023d32c3c3' User entered 'Some interference with activity (2)' | System | 14 Nov 2020 04:52:54 |
| | System | 14 Nov 2020 04:52:54 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-13T21:52:50', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '165a896d-05a2-4ebe-995f-54023d32c3c3' User entered '13 Nov 2020 21:52' | System | 14 Nov 2020 04:52:54 |
| | System | 14 Nov 2020 04:52:54 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '13 Nov 2020 12:00' | System | 12 Nov 2020 04:03:55 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '14 Nov 2020 11:59' | System | 12 Nov 2020 04:03:55 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 13 Nov 2020 04:53:47 |
| User entered 'Day 13' | System | 13 Nov 2020 04:53:47 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-15T07:15:48', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '3566af87-903d-4c45-8cc9-1a0545d6bb04' | System | 15 Nov 2020 14:15:54 |
| User entered 'Some interference with activity (2)' | System | 15 Nov 2020 14:15:54 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-15T07:15:51', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '3566af87-903d-4c45-8cc9-1a0545d6bb04' User entered '15 Nov 2020 07:15' | System | 15 Nov 2020 14:15:54 |
| | System | 15 Nov 2020 14:15:54 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '14 Nov 2020 12:00' | System | 13 Nov 2020 04:53:47 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '15 Nov 2020 11:59' | System | 13 Nov 2020 04:53:47 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 14 Nov 2020 04:52:54 |
| User entered 'Day 14' | System | 14 Nov 2020 04:52:54 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '15 Nov 2020 12:00' | System | 14 Nov 2020 04:52:54 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '16 Nov 2020 11:59' | System | 14 Nov 2020 04:52:54 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 15 Nov 2020 14:15:54 |
| User entered 'Day 15' | System | 15 Nov 2020 14:15:54 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-16T12:09:30', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'a2f08fb1-4409-4ba6-9fab-2d9c7ea83644' | System | 16 Nov 2020 19:09:36 |
| User entered 'Significant; prevents daily activity (3)' | System | 16 Nov 2020 19:09:36 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-16T12:09:33', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'a2f08fb1-4409-4ba6-9fab-2d9c7ea83644' | System | 16 Nov 2020 19:09:36 |
| User entered '16 Nov 2020 12:09' | System | 16 Nov 2020 19:09:36 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '16 Nov 2020 12:00' | System | 15 Nov 2020 14:15:54 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '17 Nov 2020 11:59' | System | 15 Nov 2020 14:15:54 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 16 Nov 2020 19:09:36 |
| User entered 'Day 16' | System | 16 Nov 2020 19:09:36 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '17 Nov 2020 12:00' | System | 16 Nov 2020 19:09:36 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '18 Nov 2020 11:59' | System | 16 Nov 2020 19:09:36 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 16 Nov 2020 19:09:36 |
| User entered 'Day 17' | System | 16 Nov 2020 19:09:36 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 15:38:11

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '18 Nov 2020 12:00' | System | 16 Nov 2020 19:09:36 |

US3192734

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '19 Nov 2020 11:59' | System | 16 Nov 2020 19:09:36 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 08 Nov 2020 05:29:27 |
| User entered 'Day 8' | System | 08 Nov 2020 05:29:27 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:38:11

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-10T06:35:39', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'a7b94507-eb69-423e-876a-62e3a9729843' | System | 10 Nov 2020 13:35:44 |
| User entered 'Some interference with activity (2)' | System | 10 Nov 2020 13:35:44 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-10T06:35:42', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'a7b94507-eb69-423e-876a-62e3a9729843' User entered '10 Nov 2020 06:35' | System | 10 Nov 2020 13:35:44 |
| | System | 10 Nov 2020 13:35:44 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '09 Nov 2020 12:00' | System | 08 Nov 2020 05:29:27 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '10 Nov 2020 11:59' | System | 08 Nov 2020 05:29:27 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 09 Nov 2020 02:07:53 |
| User entered 'Day 9' | System | 09 Nov 2020 02:07:53 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 15:38:11

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-11T08:43:25', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '6c718542-3feb-4571-ad14-82ddc46b861e' User entered 'Some interference with activity (2)' | System | 11 Nov 2020 15:43:30 |
| | System | 11 Nov 2020 15:43:30 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-11T08:43:27', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '6c718542-3feb-4571-ad14-82ddc46b861e' User entered '11 Nov 2020 08:43' | System | 11 Nov 2020 15:43:30 |
| | System | 11 Nov 2020 15:43:30 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '10 Nov 2020 12:00' | System | 09 Nov 2020 02:07:53 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '11 Nov 2020 11:59' | System | 09 Nov 2020 02:07:53 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 10 Nov 2020 13:35:44 |
| User entered 'Day 10' | System | 10 Nov 2020 13:35:44 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 15:38:11

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-11T21:04:00', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '3725ee07-bfef-41a5-bdbe-245ebd568810' | System | 12 Nov 2020 04:04:09 |
| User entered 'Some interference with activity (2)' | System | 12 Nov 2020 04:04:09 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-11T21:04:02', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '3725ee07-bfef-41a5-bdbe-245ebd568810' User entered '11 Nov 2020 21:04' | System | 12 Nov 2020 04:04:09 |
| | System | 12 Nov 2020 04:04:09 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '11 Nov 2020 12:00' | System | 10 Nov 2020 13:35:44 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '12 Nov 2020 11:59' | System | 10 Nov 2020 13:35:44 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 11 Nov 2020 15:43:30 |
| User entered 'Day 11' | System | 11 Nov 2020 15:43:30 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 15:38:11

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-12T21:53:49', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'f1a26240-6bef-4110-b35e-d8886affe18d' | System | 13 Nov 2020 04:53:53 |
| User entered 'Some interference with activity (2)' | System | 13 Nov 2020 04:53:53 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-12T21:53:51', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'f1a26240-6bef-4110-b35e-d8886affe18d' User entered '12 Nov 2020 21:53' | System | 13 Nov 2020 04:53:53 |
| | System | 13 Nov 2020 04:53:53 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '12 Nov 2020 12:00' | System | 11 Nov 2020 15:43:30 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '13 Nov 2020 11:59' | System | 11 Nov 2020 15:43:30 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 12 Nov 2020 04:04:09 |
| User entered 'Day 12' | System | 12 Nov 2020 04:04:09 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 15:38:11

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-13T21:52:54', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'a8d8dd06-a383-48af-93d1-6c630be8ea51' | System | 14 Nov 2020 04:53:01 |
| User entered 'No interference with activity (1)' | System | 14 Nov 2020 04:53:01 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-13T21:52:56', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'a8d8dd06-a383-48af-93d1-6c630be8ea51' User entered '13 Nov 2020 21:52' | System | 14 Nov 2020 04:53:01 |
| | System | 14 Nov 2020 04:53:01 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '13 Nov 2020 12:00' | System | 12 Nov 2020 04:04:09 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '14 Nov 2020 11:59' | System | 12 Nov 2020 04:04:09 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 13 Nov 2020 04:53:53 |
| User entered 'Day 13' | System | 13 Nov 2020 04:53:53 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 15:38:11

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-15T07:15:59', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '4b7d3048-8d89-4765-918c-48fcd182735' | System | 15 Nov 2020 14:16:05 |
| User entered 'No interference with activity (1)' | System | 15 Nov 2020 14:16:05 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-15T07:16:01', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '4b7d3048-8d89-4765-918c-48fcdb182735' | System | 15 Nov 2020 14:16:05 |
| User entered '15 Nov 2020 07:16' | System | 15 Nov 2020 14:16:05 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '14 Nov 2020 12:00' | System | 13 Nov 2020 04:53:53 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '15 Nov 2020 11:59' | System | 13 Nov 2020 04:53:53 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 14 Nov 2020 04:53:01 |
| User entered 'Day 14' | System | 14 Nov 2020 04:53:01 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 15:38:11

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '15 Nov 2020 12:00' | System | 14 Nov 2020 04:53:01 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '16 Nov 2020 11:59' | System | 14 Nov 2020 04:53:01 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 15 Nov 2020 14:16:05 |
| User entered 'Day 15' | System | 15 Nov 2020 14:16:05 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 15:38:11

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-16T12:09:39', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '461fc40c-cbe7-4fe6-941e-27397077a9cc' | System | 16 Nov 2020 19:09:46 |
| User entered 'Some interference with activity (2)' | System | 16 Nov 2020 19:09:46 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-16T12:09:43', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '461fc40c-cbe7-4fe6-941e-27397077a9cc' | System | 16 Nov 2020 19:09:46 |
| User entered '16 Nov 2020 12:09' | System | 16 Nov 2020 19:09:46 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '16 Nov 2020 12:00' | System | 15 Nov 2020 14:16:05 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '17 Nov 2020 11:59' | System | 15 Nov 2020 14:16:05 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 16 Nov 2020 19:09:46 |
| User entered 'Day 16' | System | 16 Nov 2020 19:09:46 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 15:38:11

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '17 Nov 2020 12:00' | System | 16 Nov 2020 19:09:46 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '18 Nov 2020 11:59' | System | 16 Nov 2020 19:09:46 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 16 Nov 2020 19:09:46 |
| User entered 'Day 17' | System | 16 Nov 2020 19:09:46 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 15:38:11

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '18 Nov 2020 12:00' | System | 16 Nov 2020 19:09:46 |

US3192734

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '19 Nov 2020 11:59' | System | 16 Nov 2020 19:09:46 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 08 Nov 2020 05:29:27 |
| User entered 'Day 8' | System | 08 Nov 2020 05:29:27 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-10T06:35:47', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'be0d4c9c-e130-454a-ba8a-8d1af164735d' User entered 'Some interference with activity (2)' | System | 10 Nov 2020 13:35:52 |
| | System | 10 Nov 2020 13:35:52 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-10T06:35:49', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'be0d4c9c-e130-454a-ba8a-8d1af164735d' User entered '10 Nov 2020 06:35' | System | 10 Nov 2020 13:35:52 |
| | System | 10 Nov 2020 13:35:52 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '09 Nov 2020 12:00' | System | 08 Nov 2020 05:29:27 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '10 Nov 2020 11:59' | System | 08 Nov 2020 05:29:27 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 09 Nov 2020 02:07:53 |
| User entered 'Day 9' | System | 09 Nov 2020 02:07:53 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-11T08:43:32', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'baa43e3a-f391-4867-a2ca-5f500122b656' | System | 11 Nov 2020 15:43:37 |
| User entered 'Some interference with activity (2)' | System | 11 Nov 2020 15:43:37 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-11T08:43:34', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'baa43e3a-f391-4867-a2ca-5f500122b656' User entered '11 Nov 2020 08:43' | System | 11 Nov 2020 15:43:37 |
| | System | 11 Nov 2020 15:43:37 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '10 Nov 2020 12:00' | System | 09 Nov 2020 02:07:53 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '11 Nov 2020 11:59' | System | 09 Nov 2020 02:07:53 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 10 Nov 2020 13:35:52 |
| User entered 'Day 10' | System | 10 Nov 2020 13:35:52 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-11T21:04:06', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '6ce832f7-c4b8-426e-b197-38bc8946f582' | System | 12 Nov 2020 04:04:12 |
| User entered 'Some interference with activity (2)' | System | 12 Nov 2020 04:04:12 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-11T21:04:08', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '6ce832f7-c4b8-426e-b197-38bc8946f582' User entered '11 Nov 2020 21:04' | System | 12 Nov 2020 04:04:12 |
| | System | 12 Nov 2020 04:04:12 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '11 Nov 2020 12:00' | System | 10 Nov 2020 13:35:52 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '12 Nov 2020 11:59' | System | 10 Nov 2020 13:35:52 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 11 Nov 2020 15:43:37 |
| User entered 'Day 11' | System | 11 Nov 2020 15:43:37 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-12T21:53:56', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '760f50e2-2e4a-4ffa-9176-9a6e04103129' | System | 13 Nov 2020 04:54:02 |
| User entered 'No interference with activity (1)' | System | 13 Nov 2020 04:54:02 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-12T21:53:59', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '760f50e2-2e4a-4ffa-9176-9a6e04103129' User entered '12 Nov 2020 21:53' | System | 13 Nov 2020 04:54:02 |
| | System | 13 Nov 2020 04:54:02 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '12 Nov 2020 12:00' | System | 11 Nov 2020 15:43:37 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '13 Nov 2020 11:59' | System | 11 Nov 2020 15:43:37 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 12 Nov 2020 04:04:12 |
| User entered 'Day 12' | System | 12 Nov 2020 04:04:12 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-13T21:53:00', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'acfa8e68-2499-4ee7-b9f1-2f6e1f4e09e0' | System | 14 Nov 2020 04:53:07 |
| User entered 'No interference with activity (1)' | System | 14 Nov 2020 04:53:07 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-13T21:53:02', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'acfa8e68-2499-4ee7-b9f1-2f6e1f4e09e0' User entered '13 Nov 2020 21:53' | System | 14 Nov 2020 04:53:07 |
| | System | 14 Nov 2020 04:53:07 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '13 Nov 2020 12:00' | System | 12 Nov 2020 04:04:12 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '14 Nov 2020 11:59' | System | 12 Nov 2020 04:04:12 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 13 Nov 2020 04:54:02 |
| User entered 'Day 13' | System | 13 Nov 2020 04:54:02 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-15T07:16:06', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'a39f8980-fb08-406a-abd2-1cbc5a28e7ef' User entered 'No interference with activity (1)' | System | 15 Nov 2020 14:16:10 |
| | System | 15 Nov 2020 14:16:10 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-15T07:16:08', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'a39f8980-fb08-406a-abd2-1cbc5a28e7ef' User entered '15 Nov 2020 07:16' | System | 15 Nov 2020 14:16:10 |
| | System | 15 Nov 2020 14:16:10 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '14 Nov 2020 12:00' | System | 13 Nov 2020 04:54:02 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '15 Nov 2020 11:59' | System | 13 Nov 2020 04:54:02 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 14 Nov 2020 04:53:07 |
| User entered 'Day 14' | System | 14 Nov 2020 04:53:07 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '15 Nov 2020 12:00' | System | 14 Nov 2020 04:53:07 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '16 Nov 2020 11:59' | System | 14 Nov 2020 04:53:07 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 15 Nov 2020 14:16:10 |
| User entered 'Day 15' | System | 15 Nov 2020 14:16:10 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-16T12:09:47', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '0bee49f4-d068-4861-a37c-d557fc4784b1' | System | 16 Nov 2020 19:09:52 |
| User entered 'No interference with activity (1)' | System | 16 Nov 2020 19:09:52 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-16T12:09:50', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '0bee49f4-d068-4861-a37c-d557fc4784b1' User entered '16 Nov 2020 12:09' | System | 16 Nov 2020 19:09:52 |
| | System | 16 Nov 2020 19:09:52 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '16 Nov 2020 12:00' | System | 15 Nov 2020 14:16:10 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '17 Nov 2020 11:59' | System | 15 Nov 2020 14:16:10 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 16 Nov 2020 19:09:52 |
| User entered 'Day 16' | System | 16 Nov 2020 19:09:52 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '17 Nov 2020 12:00' | System | 16 Nov 2020 19:09:52 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '18 Nov 2020 11:59' | System | 16 Nov 2020 19:09:52 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 16 Nov 2020 19:09:52 |
| User entered 'Day 17' | System | 16 Nov 2020 19:09:52 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '18 Nov 2020 12:00' | System | 16 Nov 2020 19:09:52 |

US3192734

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '19 Nov 2020 11:59' | System | 16 Nov 2020 19:09:52 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 08 Nov 2020 05:27:53 |
| User entered 'Day 8' | System | 08 Nov 2020 05:27:53 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-10T06:35:53', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '971cd0a6-d217-45b3-a41e-e7c22ee8211c' User entered 'No (N)' | System | 10 Nov 2020 13:35:59 |
| | System | 10 Nov 2020 13:35:59 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-10T06:35:57', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '971cd0a6-d217-45b3-a41e-e7c22ee8211c' User entered '10 Nov 2020 06:35' | System | 10 Nov 2020 13:35:59 |
| | System | 10 Nov 2020 13:35:59 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '09 Nov 2020 12:00' | System | 08 Nov 2020 05:27:53 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '10 Nov 2020 11:59' | System | 08 Nov 2020 05:27:53 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 09 Nov 2020 02:06:41 |
| User entered 'Day 9' | System | 09 Nov 2020 02:06:41 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-11T08:43:39', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'f7a15fe8-8f0a-4810-a06d-18ef725a9bad' User entered 'Yes (Y)' | System | 11 Nov 2020 15:43:45 |
| | System | 11 Nov 2020 15:43:45 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-11T08:43:42', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'f7a15fe8-8f0a-4810-a06d-18ef725a9bad' User entered '11 Nov 2020 08:43' | System | 11 Nov 2020 15:43:45 |
| | System | 11 Nov 2020 15:43:45 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '10 Nov 2020 12:00' | System | 09 Nov 2020 02:06:41 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '11 Nov 2020 11:59' | System | 09 Nov 2020 02:06:41 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 10 Nov 2020 13:35:02 |
| User entered 'Day 10' | System | 10 Nov 2020 13:35:02 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-11T21:04:26', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '8e3fdf80-11ba-4a2b-adb7-a1f748798bf8' User entered 'Yes (Y)' | System | 12 Nov 2020 04:04:34 |
| | System | 12 Nov 2020 04:04:34 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-11T21:04:31', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '8e3fdf80-11ba-4a2b-adb7-a1f748798bf8' User entered '11 Nov 2020 21:04' | System | 12 Nov 2020 04:04:34 |
| | System | 12 Nov 2020 04:04:34 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '11 Nov 2020 12:00' | System | 10 Nov 2020 13:35:02 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '12 Nov 2020 11:59' | System | 10 Nov 2020 13:35:02 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 11 Nov 2020 15:43:15 |
| User entered 'Day 11' | System | 11 Nov 2020 15:43:15 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-12T21:54:03', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'c4adab5b-f9d9-4d28-8c62-d7eca3bc37ab' User entered 'No (N)' | System | 13 Nov 2020 04:54:08 |
| | System | 13 Nov 2020 04:54:08 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-12T21:54:06', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'c4adab5b-f9d9-4d28-8c62-d7eca3bc37ab' User entered '12 Nov 2020 21:54' | System | 13 Nov 2020 04:54:08 |
| | System | 13 Nov 2020 04:54:08 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '12 Nov 2020 12:00' | System | 11 Nov 2020 15:43:15 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '13 Nov 2020 11:59' | System | 11 Nov 2020 15:43:15 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 12 Nov 2020 04:03:40 |
| User entered 'Day 12' | System | 12 Nov 2020 04:03:40 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '13 Nov 2020 12:00' | System | 12 Nov 2020 04:03:40 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '14 Nov 2020 11:59' | System | 12 Nov 2020 04:03:40 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 13 Nov 2020 04:53:40 |
| User entered 'Day 13' | System | 13 Nov 2020 04:53:40 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-15T07:16:12', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '47083b90-6875-44d3-b17e-cc495f6ed975' | System | 15 Nov 2020 14:16:20 |
| User entered 'Yes (Y)' | System | 15 Nov 2020 14:16:20 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-15T07:16:17', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '47083b90-6875-44d3-b17e-cc495f6ed975' User entered '15 Nov 2020 07:16' | System | 15 Nov 2020 14:16:20 |
| | System | 15 Nov 2020 14:16:20 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '14 Nov 2020 12:00' | System | 13 Nov 2020 04:53:40 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '15 Nov 2020 11:59' | System | 13 Nov 2020 04:53:40 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 14 Nov 2020 04:52:48 |
| User entered 'Day 14' | System | 14 Nov 2020 04:52:48 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '15 Nov 2020 12:00' | System | 14 Nov 2020 04:52:48 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '16 Nov 2020 11:59' | System | 14 Nov 2020 04:52:48 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 15 Nov 2020 14:15:35 |
| User entered 'Day 15' | System | 15 Nov 2020 14:15:35 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-16T12:09:54', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '8ae211ea-8db2-4385-90d6-a8688e32c6b5' User entered 'Yes (Y)' | System | 16 Nov 2020 19:10:02 |
| | System | 16 Nov 2020 19:10:02 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-11-16T12:09:59', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '8ae211ea-8db2-4385-90d6-a8688e32c6b5' User entered '16 Nov 2020 12:09' | System | 16 Nov 2020 19:10:02 |
| | System | 16 Nov 2020 19:10:02 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '16 Nov 2020 12:00' | System | 15 Nov 2020 14:15:35 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '17 Nov 2020 11:59' | System | 15 Nov 2020 14:15:35 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 16 Nov 2020 19:09:29 |
| User entered 'Day 16' | System | 16 Nov 2020 19:09:29 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '17 Nov 2020 12:00' | System | 16 Nov 2020 19:09:29 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '18 Nov 2020 11:59' | System | 16 Nov 2020 19:09:29 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| Data entry locked. | System | 16 Nov 2020 19:09:29 |
| User entered 'Day 17' | System | 16 Nov 2020 19:09:29 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 15:38:11

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 19:55:14 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 15:38:11

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 15:38:11

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '18 Nov 2020 12:00' | System | 16 Nov 2020 19:09:29 |

US3192734

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 15:38:11

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:55:14 |
| User entered '19 Nov 2020 11:59' | System | 16 Nov 2020 19:09:29 |

US3192734

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:43:38 |
| User closed query 'Per CDM: Data is required. Please enter a response and complete form as appropriate. ' (Site from DM). | | 26 Apr 2021 03:50:59 |
| User signature succeeded. | John McGettigan (b) (4) | 25 Apr 2021 17:54:10 |
| Query 'Per CDM: Data is required. Please enter a response and complete form as appropriate. ' answered with 'updated' (Site from DM). | (b) (4) (b) (4), (b) (6) | 23 Apr 2021 23:32:16 |
| Signature has been broken. | | 23 Apr 2021 23:31:56 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | | 23 Apr 2021 23:31:56 |
| User opened query 'Per CDM: Data is required. Please enter a response and complete form as appropriate. ' (Site from DM). | | 22 Apr 2021 21:59:27 |
| Data hard unlocked. | | 22 Apr 2021 20:21:39 |
| Data hard locked. | | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 13:59:24 |
| Query 'Data is required. Please complete.' answered with 'in window of the safety call ' (Site from System). | maggie Tono (b) (4) (b) (4) | 05 Nov 2020 23:17:43 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 02 Nov 2020 22:29:39 |
| User entered empty; reason for change Data Entry Error | Saysamone Banks (b) (4) (b) (4) | 02 Nov 2020 22:29:39 |
| User entered 'Yes (Y)' | Saysamone Banks (b) (4) (b) (4) | 02 Nov 2020 22:28:31 |

US3192734

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:43:38 |
| User signature succeeded. | John McGettigan (b) (4) | 25 Apr 2021 17:54:10 |
| Signature has been broken. | (b) (4) (b) (4), (b) (6) | 23 Apr 2021 23:31:56 |
| User entered '10 Nov 2020' reason for change: Data Entry Error | | 23 Apr 2021 23:31:56 |
| Data hard unlocked. | | 22 Apr 2021 20:21:39 |
| Data hard locked. | | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | (b) (4) System | 02 Nov 2020 22:29:39 |
| Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System). | System | 02 Nov 2020 22:29:39 |
| User entered empty; reason for change Data Entry Error | Saysamone Banks (b) (4) (b) (4) | 02 Nov 2020 22:29:39 |
| User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | System | 02 Nov 2020 22:28:31 |
| User entered '10 Oct 2020' | Saysamone Banks (b) (4) (b) (4) | 02 Nov 2020 22:28:31 |

US3192734

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:43:38 |
| User signature succeeded. | John McGettigan (b) (4) | 25 Apr 2021 17:54:10 |
| Signature has been broken. | (b) (4) (b) (4), (b) (6) | 23 Apr 2021 23:31:56 |
| User entered 'Contact Made (CONTACT MADE)' | | 23 Apr 2021 23:31:56 |
| reason for change: Data Entry Error | | 22 Apr 2021 20:21:39 |
| Data hard unlocked. | | 28 Mar 2021 00:13:04 |
| Data hard locked. | | |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered empty; reason for change Data Entry Error | (b) (4) Saysamone Banks (b) (4) | 02 Nov 2020 22:29:39 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Saysamone Banks (b) (4) | 02 Nov 2020 22:28:31 |
| | (b) (4) | |

US3192734

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:43:38 |
| Data hard unlocked. | | 22 Apr 2021 20:21:39 |
| Data hard locked. | | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered empty. | (b) (4) Saysamone Banks (b) (4) (b) (4) | 02 Nov 2020 22:28:31 |

US3192734

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered 'Yes (Y)' | maggie Tono (b) (4) | 05 Nov 2020 23:17:08 |

US3192734

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:11

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered 'I' | System | 05 Nov 2020 23:17:08 |

US3192734

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 20:55:12 |

US3192734

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered '19 Nov 2020' | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 20:55:12 |

US3192734

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 20:55:12 |

US3192734

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 20:55:12 |

US3192734

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 20:55:21 |

US3192734

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:11

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered 'I' | System | 25 Nov 2020 20:55:21 |

US3192734

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 20:56:13 |

US3192734

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered '25 Nov 2020' | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 20:56:13 |

US3192734

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 20:56:13 |

US3192734

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 20:56:13 |

US3192734

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:21 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 20:56:17 |

US3192734

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:11

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered 'I' | System | 25 Nov 2020 20:56:17 |

US3192734

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:11

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Yes (Y)' | Tianna Young (b) (4) | 02 Dec 2020 21:40:31 |

US3192734

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '2 Dec 2020' | Tianna Young (b) (4) | 02 Dec 2020 21:40:31 |

US3192734

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Clinic (Clinic)' | Tianna Young (b) (4) | 02 Dec 2020 21:40:31 |

US3192734

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:11

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered 'VISIT3' | System | 02 Dec 2020 21:40:31 |

US3192734

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Yes (Y)' | Tianna Young (b) (4) | 02 Dec 2020 21:41:50 |

US3192734

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '2 Dec 2020' | Tianna Young (b) (4) | 02 Dec 2020 21:41:50 |

US3192734

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Time of assessment \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '11:30' | Tianna Young (b) (4) | 02 Dec 2020 21:41:50 |

US3192734

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered '2 Dec 2020 11:30' | System | 02 Dec 2020 21:41:50 |

US3192734

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '97.6' F | Tianna Young (b) (4) | 02 Dec 2020 21:41:50 |

US3192734

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Oral (Oral)' | Tianna Young (b) (4) | 02 Dec 2020 21:41:50 |

US3192734

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered empty. | Tianna Young (b) (4) | 02 Dec 2020 21:41:50 |

US3192734

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '89' | Tianna Young (b) (4) | 02 Dec 2020 21:41:50 |

US3192734

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered 'bpm' | System | 02 Dec 2020 21:41:50 |

US3192734

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '16' | Tianna Young (b) (4) | 02 Dec 2020 21:41:50 |

US3192734

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered 'breaths/min' | System | 02 Dec 2020 21:41:50 |

US3192734

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '89' | Tianna Young (b) (4) | 02 Dec 2020 21:41:50 |

US3192734

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered 'mmHg' | System | 02 Dec 2020 21:41:50 |

US3192734

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '72' | Tianna Young (b) (4) | 02 Dec 2020 21:41:50 |

US3192734

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered 'mmHg' | System | 02 Dec 2020 21:41:50 |

US3192734

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| | | |

US3192734

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Weight \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| | | |

US3192734

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:38:11

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Yes (Y)' | Tianna Young (b) (4) | 02 Dec 2020 21:40:46 |

US3192734

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:38:11

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '2 Dec 2020' | Tianna Young (b) (4) | 02 Dec 2020 21:40:46 |

US3192734

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:11

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Yes (Y)' | Tianna Young (b) (4) | 02 Dec 2020 21:41:07 |

US3192734

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:11

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '2 Dec 2020' | Tianna Young (b) (4) | 02 Dec 2020 21:41:07 |

US3192734

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:11

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered '11:40' | Tianna Young (b) (4) | 02 Dec 2020 21:41:07 |

US3192734

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered '2 Dec 2020 11:40' | System | 02 Dec 2020 21:41:07 |

US3192734

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 14 Feb 2021 03:28:23 |
| User entered 'Yes (Y)' | Tianna Young (b) (4) | 02 Dec 2020 21:41:16 |

US3192734

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:11

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered 'I' | System | 02 Dec 2020 21:41:16 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 61' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[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 (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-12-03T11:54:55', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'af269a7a-0564-4add-891b-8a41ac71d002' User entered 'No (N)' | System | 03 Dec 2020 18:55:09 |
| | System | 03 Dec 2020 18:55:09 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

Have you been exposed to someone with 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 (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-12-03T11:55:01', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'af269a7a-0564-4add-891b-8a41ac71d002' | System | 03 Dec 2020 18:55:09 |
| User entered 'No (N)' | System | 03 Dec 2020 18:55:09 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-12-03T11:55:06', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'af269a7a-0564-4add-891b-8a41ac71d002' | System | 03 Dec 2020 18:55:09 |
| User entered '03 Dec 2020 11:55:06' | System | 03 Dec 2020 18:55:09 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '01 Dec 2020 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '05 Dec 2020 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 68' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '08 Dec 2020 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '12 Dec 2020 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 75' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[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 (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-12-17T12:00:24', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'e3fbce4b-6b67-46a1-ba7e-8a3002d0656b' User entered 'No (N)' | System | 17 Dec 2020 19:00:38 |
| | System | 17 Dec 2020 19:00:38 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

Have you been exposed to someone with 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 (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-12-17T12:00:28', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'e3fbce4b-6b67-46a1-ba7e-8a3002d0656b' User entered 'No (N)' | System | 17 Dec 2020 19:00:38 |
| | System | 17 Dec 2020 19:00:38 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-12-17T12:00:32', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'e3fbce4b-6b67-46a1-ba7e-8a3002d0656b' User entered '17 Dec 2020 12:00:32' | System | 17 Dec 2020 19:00:38 |
| | System | 17 Dec 2020 19:00:38 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '15 Dec 2020 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '19 Dec 2020 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 82' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[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 (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-12-26T11:59:53', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '995a7d25-dd23-4c88-ab69-af75b5573866' User entered 'No (N)' | System | 26 Dec 2020 19:00:07 |
| | System | 26 Dec 2020 19:00:07 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

Have you been exposed to someone with 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 (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-12-26T11:59:57', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '995a7d25-dd23-4c88-ab69-af75b5573866' | System | 26 Dec 2020 19:00:07 |
| User entered 'No (N)' | System | 26 Dec 2020 19:00:07 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-12-26T12:00:03', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '995a7d25-dd23-4c88-ab69-af75b5573866' User entered '26 Dec 2020 12:00:03' | System | 26 Dec 2020 19:00:07 |
| | System | 26 Dec 2020 19:00:07 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '22 Dec 2020 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '26 Dec 2020 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 89' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[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 (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-12-29T08:25:28', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '0f6937eb-06f5-47a3-8113-1ae340f8c5b9' User entered 'No (N)' | System | 29 Dec 2020 15:25:54 |
| | System | 29 Dec 2020 15:25:54 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

Have you been exposed to someone with 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 (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-12-29T08:25:32', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '0f6937eb-06f5-47a3-8113-1ae340f8c5b9' User entered 'No (N)' | System | 29 Dec 2020 15:25:54 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2020-12-29T08:25:37', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '0f6937eb-06f5-47a3-8113-1ae340f8c5b9' User entered '29 Dec 2020 08:25:37' | System | 29 Dec 2020 15:25:54 |
| | System | 29 Dec 2020 15:25:54 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '29 Dec 2020 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '02 Jan 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 96' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[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 (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-01-05T08:10:47', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'e49be2ce-141c-4c78-b395-e03e67229996' User entered 'No (N)' | System | 05 Jan 2021 15:11:00 |
| | System | 05 Jan 2021 15:11:00 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

Have you been exposed to someone with 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 (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-01-05T08:10:52', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'e49be2ce-141c-4c78-b395-e03e67229996' | System | 05 Jan 2021 15:11:00 |
| User entered 'No (N)' | System | 05 Jan 2021 15:11:00 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-01-05T08:10:57', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'e49be2ce-141c-4c78-b395-e03e67229996' User entered '05 Jan 2021 08:10:57' | System | 05 Jan 2021 15:11:00 |
| | System | 05 Jan 2021 15:11:00 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '05 Jan 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '09 Jan 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 103' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[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 (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-01-14T12:00:47', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '5e636e9f-f213-4d28-9ec8-e91c7b6c18ee' User entered 'No (N)' | System | 14 Jan 2021 19:01:01 |
| | System | 14 Jan 2021 19:01:01 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Have you been exposed to someone with 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 (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-01-14T12:00:51', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '5e636e9f-f213-4d28-9ec8-e91c7b6c18ee' User entered 'No (N)' | System | 14 Jan 2021 19:01:01 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-01-14T12:00:57', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '5e636e9f-f213-4d28-9ec8-e91c7b6c18ee' User entered '14 Jan 2021 12:00:57' | System | 14 Jan 2021 19:01:01 |
| | System | 14 Jan 2021 19:01:01 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '12 Jan 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '16 Jan 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 110' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[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 (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-01-21T12:06:14', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '2075f848-128b-40fb-82df-4eb47aa19cdc' User entered 'No (N)' | System | 21 Jan 2021 19:06:23 |
| | System | 21 Jan 2021 19:06:23 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

Have you been exposed to someone with 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 (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-01-21T12:06:17', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '2075f848-128b-40fb-82df-4eb47aa19cdc' User entered 'No (N)' | System | 21 Jan 2021 19:06:23 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-01-21T12:06:20', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '2075f848-128b-40fb-82df-4eb47aa19cdc' User entered '21 Jan 2021 12:06:20' | System | 21 Jan 2021 19:06:23 |
| | System | 21 Jan 2021 19:06:23 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '19 Jan 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '23 Jan 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 117' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[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 (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-01-26T08:56:09', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '1e915b15-6ba9-4e27-9796-fb290157500b' User entered 'No (N)' | System | 26 Jan 2021 15:57:34 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

Have you been exposed to someone with 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 (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-01-26T08:56:19', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '1e915b15-6ba9-4e27-9796-fb290157500b' User entered 'No (N)' | System | 26 Jan 2021 15:57:34 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-01-26T08:56:22', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '1e915b15-6ba9-4e27-9796-fb290157500b' User entered '26 Jan 2021 08:56:22' | System | 26 Jan 2021 15:57:34 |
| | System | 26 Jan 2021 15:57:34 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '26 Jan 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '30 Jan 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 124' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[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 (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-02-02T07:27:04', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '751d6e8c-c505-4694-a173-9cc45d802e4b' User entered 'No (N)' | System | 02 Feb 2021 14:27:18 |
| | System | 02 Feb 2021 14:27:18 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

Have you been exposed to someone with 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 (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-02-02T07:27:11', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '751d6e8c-c505-4694-a173-9cc45d802e4b' | System | 02 Feb 2021 14:27:18 |
| User entered 'No (N)' | System | 02 Feb 2021 14:27:18 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-02-02T07:27:15', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '751d6e8c-c505-4694-a173-9cc45d802e4b' User entered '02 Feb 2021 07:27:15' | System | 02 Feb 2021 14:27:18 |
| | System | 02 Feb 2021 14:27:18 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '02 Feb 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '06 Feb 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 131' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[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 (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-02-09T08:32:19', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '30c8f522-19a4-4f32-b000-596be05dd5d0' User entered 'No (N)' | System | 09 Feb 2021 15:32:31 |
| | System | 09 Feb 2021 15:32:31 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

Have you been exposed to someone with 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 (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-02-09T08:32:23', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '30c8f522-19a4-4f32-b000-596be05dd5d0' User entered 'No (N)' | System | 09 Feb 2021 15:32:31 |
| | System | 09 Feb 2021 15:32:31 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-02-09T08:32:29', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '30c8f522-19a4-4f32-b000-596be05dd5d0' User entered '09 Feb 2021 08:32:29' | System | 09 Feb 2021 15:32:31 |
| | System | 09 Feb 2021 15:32:31 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '09 Feb 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '13 Feb 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 138' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[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 (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-02-16T21:27:33', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '291df714-9c06-468c-afc4-8012520ed0ff' User entered 'No (N)' | System | 17 Feb 2021 04:27:41 |
| | System | 17 Feb 2021 04:27:41 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

Have you been exposed to someone with 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 (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-02-16T21:27:36', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '291df714-9c06-468c-afc4-8012520ed0ff' User entered 'No (N)' | System | 17 Feb 2021 04:27:41 |
| | System | 17 Feb 2021 04:27:41 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-02-16T21:27:39', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '291df714-9c06-468c-afc4-8012520ed0ff' User entered '16 Feb 2021 21:27:39' | System | 17 Feb 2021 04:27:41 |
| | System | 17 Feb 2021 04:27:41 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '16 Feb 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '20 Feb 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 145' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '23 Feb 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '27 Feb 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 152' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[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 (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-03-02T07:33:47-07:00', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '1a052017-6c46-4412-8132-17c353305ba4' | System | 02 Mar 2021 14:33:57 |
| User entered 'No (N)' | System | 02 Mar 2021 14:33:57 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

Have you been exposed to someone with 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 (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-03-02T07:33:50-07:00', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '1a052017-6c46-4412-8132-17c353305ba4' | System | 02 Mar 2021 14:33:57 |
| User entered 'No (N)' | System | 02 Mar 2021 14:33:57 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-03-02T07:33:54-07:00', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '1a052017-6c46-4412-8132-17c353305ba4' | System | 02 Mar 2021 14:33:57 |
| User entered '02 Mar 2021 07:33:54' | System | 02 Mar 2021 14:33:57 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '02 Mar 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '06 Mar 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 159' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[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 (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-03-09T07:16:20-07:00', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '84bd85e7-35a3-4200-b342-832525b5f97c' | System | 09 Mar 2021 14:16:33 |
| User entered 'No (N)' | System | 09 Mar 2021 14:16:33 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

Have you been exposed to someone with 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 (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-03-09T07:16:25-07:00', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '84bd85e7-35a3-4200-b342-832525b5f97c' | System | 09 Mar 2021 14:16:33 |
| User entered 'No (N)' | System | 09 Mar 2021 14:16:33 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-03-09T07:16:30-07:00', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '84bd85e7-35a3-4200-b342-832525b5f97c' | System | 09 Mar 2021 14:16:33 |
| User entered '09 Mar 2021 07:16:30' | System | 09 Mar 2021 14:16:33 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '09 Mar 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '13 Mar 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 166' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[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 (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-03-16T08:47:09-07:00', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'bae1ff30-0a37-41b4-a7fe-ffe231462888' | System | 16 Mar 2021 15:47:20 |
| User entered 'No (N)' | System | 16 Mar 2021 15:47:20 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

Have you been exposed to someone with 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 (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-03-16T08:47:12-07:00', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'bae1ff30-0a37-41b4-a7fe-ffe231462888' | System | 16 Mar 2021 15:47:20 |
| User entered 'No (N)' | System | 16 Mar 2021 15:47:20 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-03-16T08:47:15-07:00', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'bae1ff30-0a37-41b4-a7fe-ffe231462888' | System | 16 Mar 2021 15:47:20 |
| User entered '16 Mar 2021 08:47:15' | System | 16 Mar 2021 15:47:20 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '16 Mar 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '20 Mar 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 173' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[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 (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-03-23T07:46:45-10:00', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '85f4e113-4ad1-4f42-876d-4ef34c69a296' | System | 23 Mar 2021 17:46:59 |
| User entered 'No (N)' | System | 23 Mar 2021 17:46:59 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

Have you been exposed to someone with 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 (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-03-23T07:46:49-10:00', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '85f4e113-4ad1-4f42-876d-4ef34c69a296' | System | 23 Mar 2021 17:46:59 |
| User entered 'No (N)' | System | 23 Mar 2021 17:46:59 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-03-23T07:46:53-10:00', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '85f4e113-4ad1-4f42-876d-4ef34c69a296' User entered '23 Mar 2021 07:46:53' | System | 23 Mar 2021 17:46:59 |
| | System | 23 Mar 2021 17:46:59 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '23 Mar 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '27 Mar 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 180' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[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 (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-04-02T08:08:20-07:00', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'f2da3f29-1a49-4391-9137-b86140e6c29c' | System | 02 Apr 2021 15:08:33 |
| User entered 'No (N)' | System | 02 Apr 2021 15:08:33 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

Have you been exposed to someone with 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 (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-04-02T08:08:24-07:00', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'f2da3f29-1a49-4391-9137-b86140e6c29c' | System | 02 Apr 2021 15:08:33 |
| User entered 'No (N)' | System | 02 Apr 2021 15:08:33 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-04-02T08:08:28-07:00', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'f2da3f29-1a49-4391-9137-b86140e6c29c' | System | 02 Apr 2021 15:08:33 |
| User entered '02 Apr 2021 08:08:28' | System | 02 Apr 2021 15:08:33 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '30 Mar 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '03 Apr 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 187' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[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 (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-04-06T08:32:24-07:00', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '3d886f2c-7016-42b8-96e9-5d0c37756144' | System | 06 Apr 2021 15:33:05 |
| User entered 'No (N)' | System | 06 Apr 2021 15:33:05 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

Have you been exposed to someone with 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 (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-04-06T08:32:26-07:00', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '3d886f2c-7016-42b8-96e9-5d0c37756144' | System | 06 Apr 2021 15:33:05 |
| User entered 'No (N)' | System | 06 Apr 2021 15:33:05 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-04-06T08:32:29-07:00', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '3d886f2c-7016-42b8-96e9-5d0c37756144' | System | 06 Apr 2021 15:33:05 |
| User entered '06 Apr 2021 08:32:29' | System | 06 Apr 2021 15:33:05 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '06 Apr 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '10 Apr 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 194' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[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 (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-04-13T07:34:50-07:00', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '1f200754-b413-48f6-b131-384acf2a0172' | System | 13 Apr 2021 14:35:04 |
| User entered 'No (N)' | System | 13 Apr 2021 14:35:04 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

Have you been exposed to someone with 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 (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-04-13T07:34:54-07:00', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '1f200754-b413-48f6-b131-384acf2a0172' | System | 13 Apr 2021 14:35:04 |
| User entered 'No (N)' | System | 13 Apr 2021 14:35:04 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-04-13T07:34:57-07:00', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '1f200754-b413-48f6-b131-384acf2a0172' | System | 13 Apr 2021 14:35:04 |
| User entered '13 Apr 2021 07:34:57' | System | 13 Apr 2021 14:35:04 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '13 Apr 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '17 Apr 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 201' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[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 (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-04-21T11:59:04-07:00', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '637016e5-f215-45bf-827c-041070f6aa80' | System | 21 Apr 2021 18:59:14 |
| User entered 'No (N)' | System | 21 Apr 2021 18:59:14 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

Have you been exposed to someone with 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 (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-04-21T11:59:07-07:00', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '637016e5-f215-45bf-827c-041070f6aa80' | System | 21 Apr 2021 18:59:14 |
| User entered 'No (N)' | System | 21 Apr 2021 18:59:14 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-04-21T11:59:11-07:00', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '637016e5-f215-45bf-827c-041070f6aa80' | System | 21 Apr 2021 18:59:14 |
| User entered '21 Apr 2021 11:59:11' | System | 21 Apr 2021 18:59:14 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '20 Apr 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '24 Apr 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 208' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[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 (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-04-27T07:08:37-07:00', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'bceb8389-92c2-42e2-ad7b-6ac891f05385' | System | 29 Apr 2021 01:41:52 |
| User entered 'No (N)' | System | 29 Apr 2021 01:41:52 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

Have you been exposed to someone with 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 (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-04-27T07:08:41-07:00', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'bceb8389-92c2-42e2-ad7b-6ac891f05385' | System | 29 Apr 2021 01:41:52 |
| User entered 'No (N)' | System | 29 Apr 2021 01:41:52 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-04-27T07:08:45-07:00', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: 'bceb8389-92c2-42e2-ad7b-6ac891f05385' | System | 29 Apr 2021 01:41:52 |
| User entered '27 Apr 2021 07:08:45' | System | 29 Apr 2021 01:41:52 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '27 Apr 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '01 May 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 215' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '04 May 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '08 May 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 222' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '11 May 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '15 May 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 229' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '18 May 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '22 May 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 236' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '25 May 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '29 May 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 243' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '01 Jun 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '05 Jun 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 250' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '08 Jun 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '12 Jun 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 257' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '15 Jun 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '19 Jun 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 264' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '22 Jun 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '26 Jun 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 271' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '29 Jun 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '03 Jul 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 278' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '06 Jul 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '10 Jul 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 285' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '13 Jul 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '17 Jul 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 292' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '20 Jul 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '24 Jul 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 299' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '27 Jul 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '31 Jul 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 306' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '03 Aug 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '07 Aug 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 313' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '10 Aug 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '14 Aug 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 320' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '17 Aug 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '21 Aug 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 327' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '24 Aug 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '28 Aug 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 334' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '31 Aug 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '04 Sep 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 341' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '07 Sep 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '11 Sep 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 348' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '14 Sep 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '18 Sep 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 355' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '21 Sep 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '25 Sep 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 362' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '28 Sep 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '02 Oct 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 369' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '05 Oct 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '09 Oct 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 376' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '12 Oct 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '16 Oct 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 383' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '19 Oct 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '23 Oct 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 390' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '26 Oct 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '30 Oct 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 397' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '02 Nov 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '06 Nov 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 404' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '09 Nov 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '13 Nov 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 411' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '16 Nov 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '20 Nov 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 418' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '23 Nov 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '27 Nov 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 425' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '30 Nov 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '04 Dec 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 432' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '07 Dec 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '11 Dec 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 439' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '14 Dec 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '18 Dec 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 446' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '21 Dec 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '25 Dec 2021 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 453' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '28 Dec 2021 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '01 Jan 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 460' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '04 Jan 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '08 Jan 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 467' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '11 Jan 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '15 Jan 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 474' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '18 Jan 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '22 Jan 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 481' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '25 Jan 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '29 Jan 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 488' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '01 Feb 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '05 Feb 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 495' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '08 Feb 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '12 Feb 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 502' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '15 Feb 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '19 Feb 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 509' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '22 Feb 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '26 Feb 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 516' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '01 Mar 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '05 Mar 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 523' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '08 Mar 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '12 Mar 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 530' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '15 Mar 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '19 Mar 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 537' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '22 Mar 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '26 Mar 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 544' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '29 Mar 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '02 Apr 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 551' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '05 Apr 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '09 Apr 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 558' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '12 Apr 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '16 Apr 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 565' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '19 Apr 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '23 Apr 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 572' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '26 Apr 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '30 Apr 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 579' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '03 May 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '07 May 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 586' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '10 May 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '14 May 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 593' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '17 May 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '21 May 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 600' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '24 May 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '28 May 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 607' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '31 May 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '04 Jun 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 614' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '07 Jun 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '11 Jun 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 621' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '14 Jun 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '18 Jun 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 628' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '21 Jun 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '25 Jun 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 635' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '28 Jun 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '02 Jul 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 642' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '05 Jul 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '09 Jul 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 649' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '12 Jul 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '16 Jul 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 656' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '19 Jul 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '23 Jul 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 663' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '26 Jul 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '30 Jul 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 670' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '02 Aug 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '06 Aug 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 677' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '09 Aug 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '13 Aug 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 684' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '16 Aug 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '20 Aug 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 691' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '23 Aug 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '27 Aug 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 698' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '30 Aug 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '03 Sep 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 705' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '06 Sep 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '10 Sep 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 712' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '13 Sep 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '17 Sep 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 719' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '20 Sep 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '24 Sep 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 726' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '27 Sep 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '01 Oct 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 733' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '04 Oct 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '08 Oct 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 740' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '11 Oct 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '15 Oct 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 747' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '18 Oct 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '22 Oct 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 754' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '25 Oct 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '29 Oct 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 761' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '01 Nov 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '05 Nov 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 768' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '08 Nov 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '12 Nov 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 775' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '15 Nov 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '19 Nov 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 782' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '22 Nov 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '26 Nov 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 789' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '29 Nov 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '03 Dec 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered 'Day 796' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '06 Dec 2022 00:01' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:11

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 11:40:47 |
| Amendment Manager: User entered '10 Dec 2022 23:59' | System | 20 Nov 2020 11:40:47 |

US3192734

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:38:11

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) | 26 Apr 2021 05:28:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-03-01T09:43:17-07:00', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '7f6bba2f-7cd9-4245-9db0-70fa22da7fc1' | System | 01 Mar 2021 16:43:28 |
| User entered 'No (N)' | System | 01 Mar 2021 16:43:28 |

US3192734

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:38:11

[Date & Time of Submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 05:28:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8FCE5E3C-4C4F-41DA-ADF5-39636E6F5852)', Time: '2021-03-01T09:43:23-07:00', User OID: 'PatientReportedOutcome (US3192734)', ODM File OID: '7f6bba2f-7cd9-4245-9db0-70fa22da7fc1' User entered '01 Mar 2021 09:43:23' | System | 01 Mar 2021 16:43:28 |
| | System | 01 Mar 2021 16:43:28 |

US3192734

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 09 Mar 2021 17:36:24 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 30 Dec 2020 15:19:35 |

US3192734

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 09 Mar 2021 17:36:24 |
| User entered '29 Dec 2020' | (b) (4) (b) (4), (b) (6) | 30 Dec 2020 15:19:35 |

US3192734

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 09 Mar 2021 17:36:24 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 30 Dec 2020 15:19:35 |

US3192734

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 09 Mar 2021 17:36:24 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 30 Dec 2020 15:19:35 |

US3192734

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User signature succeeded. | John McGettigan (b) (4) | 09 Mar 2021 17:36:24 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 30 Dec 2020 15:19:41 |

US3192734

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:11

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 00:13:04 |
| User entered 'I' | System | 30 Dec 2020 15:19:41 |

US3192734

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 07:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'No (N)' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:29:34 |

US3192734

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 07:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:29:34 |

US3192734

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 07:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:29:34 |

US3192734

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 07:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:29:34 |

US3192734

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 07:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Yes (Y)' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:29:38 |

US3192734

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:11

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 07:03:38 |
| User entered 'I' | System | 16 Mar 2021 17:29:38 |

US3192734

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 07:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'No (N)' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:30:00 |

US3192734

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 07:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:30:00 |

US3192734

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 07:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:30:00 |

US3192734

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 07:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:30:00 |

US3192734

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 07:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Yes (Y)' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:30:03 |

US3192734

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:11

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 07:03:38 |
| User entered 'I' | System | 16 Mar 2021 17:30:03 |

US3192734

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 07:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'Yes (Y)' | Damaris Atondo (b) (4) | 06 Apr 2021 21:03:37 |

US3192734

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 07:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered '1 Apr 2021' | Damaris Atondo (b) (4) | 06 Apr 2021 21:03:37 |

US3192734

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 07:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Damaris Atondo (b) (4) | 06 Apr 2021 21:03:37 |

US3192734

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 07:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | (b) (4) Damaris Atondo (b) (4) | 06 Apr 2021 21:03:37 |

US3192734

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 07:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'Yes (Y)' | Damaris Atondo (b) (4) | 06 Apr 2021 21:03:42 |

US3192734

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:11

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 07:03:38 |
| User entered 'I' | System | 06 Apr 2021 21:03:42 |

US3192734

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:11

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 19 Apr 2021 20:01:44 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 16:46:09 |

US3192734

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 19 Apr 2021 20:01:44 |
| User entered '19 Apr 2021' | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 16:46:09 |

US3192734

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 19 Apr 2021 20:01:44 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 16:46:09 |

US3192734

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:11

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|--------|----------------------|
| User entered 'VISIT4' | System | 19 Apr 2021 16:46:09 |

US3192734

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 19 Apr 2021 20:01:44 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 16:47:44 |

US3192734

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 19 Apr 2021 20:01:44 |
| User entered '19 Apr 2021' | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 16:47:44 |

US3192734

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 19 Apr 2021 20:01:44 |
| User entered '09:25' | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 16:47:44 |

US3192734

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '19 Apr 2021 09:25' | System | 19 Apr 2021 16:47:44 |

US3192734

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 19 Apr 2021 20:01:44 |
| User entered '97.6' F | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 16:47:44 |

US3192734

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 19 Apr 2021 20:01:44 |
| User entered 'Oral (Oral)' | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 16:47:44 |

US3192734

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 19 Apr 2021 20:01:44 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 16:47:44 |

US3192734

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 19 Apr 2021 20:01:44 |
| User entered '78' | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 16:47:44 |

US3192734

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 19 Apr 2021 16:47:44 |

US3192734

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 19 Apr 2021 20:01:44 |
| User entered '14' | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 16:47:44 |

US3192734

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 19 Apr 2021 16:47:44 |

US3192734

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 19 Apr 2021 20:01:44 |
| User entered '119' | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 16:47:44 |

US3192734

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 19 Apr 2021 16:47:44 |

US3192734

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 19 Apr 2021 20:01:44 |
| User entered '81' | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 16:47:44 |

US3192734

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 19 Apr 2021 16:47:44 |

US3192734

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:38:11

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 19 Apr 2021 20:01:44 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 16:46:15 |

US3192734

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:38:11

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 19 Apr 2021 20:01:44 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 16:46:15 |

US3192734

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:11

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 19 Apr 2021 20:01:44 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 16:47:58 |

US3192734

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:11

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 19 Apr 2021 20:01:44 |
| User entered '19 Apr 2021' | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 16:47:58 |

US3192734

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:11

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 19 Apr 2021 20:01:44 |
| User entered '09:44' | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 16:47:58 |

US3192734

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '19 Apr 2021 09:44' | System | 19 Apr 2021 16:47:58 |

US3192734

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 19 Apr 2021 20:01:44 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Apr 2021 16:48:02 |

US3192734

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:11

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 19 Apr 2021 16:48:02 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:38:11

[Date of Contact](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered '10 Nov 2020' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:27:52 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:38:11

[Time of Contact](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User closed query 'Data is required. Please complete.' (Site from System). | | 16 Apr 2021 05:52:22 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| Query 'Data is required. Please complete.' answered with 'not collected ' (Site from System). | (b) (4) | |
| | Yvonne De Los Reyes | 07 Apr 2021 00:27:59 |
| User opened query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| | System | 07 Apr 2021 00:27:52 |
| User entered empty. | Yvonne De Los Reyes | 07 Apr 2021 00:27:52 |
| | (b) (4) | |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:38:11

[Date and Time of Contact \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User entered empty. | System | 07 Apr 2021 00:27:52 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:38:11

[Type of Contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'Safety Call (Safety Call)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:27:52 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:38:11

[Has the subject reported symptoms of SARS-COV-2?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'Yes (Y)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:27:52 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:38:11

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'Day 1 (Day 1)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:48:57 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:38:11

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered '05 Nov 2020' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:48:57 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:38:11

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered '0' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:48:57 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:38:11

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:48:57 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:38:11

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User entered empty. | System | 07 Apr 2021 00:48:57 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:38:11

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:48:57 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:38:11

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'Mild (Mild)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:48:57 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:38:11

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'Mild (Mild)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:48:57 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:38:11

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'None (None)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:48:57 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:38:11

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'None (None)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:48:57 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:38:11

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'None (None)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:48:57 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:38:11

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'Mild (Mild)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:48:57 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:38:11

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'Mild (Mild)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:48:57 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:38:11

[Headache](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'Severe (Severe)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:48:57 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:38:11

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'None (None)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:48:57 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:38:11

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'None (None)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:48:57 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:38:11

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'None (None)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:48:57 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:38:11

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'None (None)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:48:57 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:38:11

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'None (None)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:48:57 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:38:11

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'None (None)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:48:57 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:38:11

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'None (None)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:48:57 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:38:11

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'None (None)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:48:57 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:38:11

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'Day 2 (Day 2)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:21 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:38:11

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered '06 Nov 2020' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:21 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:38:11

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'I' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:21 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:38:11

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:21 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:38:11

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User entered empty. | System | 07 Apr 2021 00:49:21 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:38:11

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:21 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:38:11

[Chills](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:21 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:38:11

[Cough](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:21 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:38:11

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:21 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:38:11

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:21 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:38:11

[Fatigue](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:21 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:38:11

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:21 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:38:11

[Body Aches](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:21 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:38:11

[Headache](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:21 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:38:11

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:21 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:38:11

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:21 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:38:11

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:21 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:38:11

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:21 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:38:11

[Nausea](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:21 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:38:11

[Vomiting](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:21 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:38:11

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:21 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:38:11

[Sore Throat](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:21 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:38:11

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'Day 3 (Day 3)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:39 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:38:11

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered '07 Nov 2020' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:39 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:38:11

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'I' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:39 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:38:11

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:39 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:38:11

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User entered empty. | System | 07 Apr 2021 00:49:39 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:38:11

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:39 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:38:11

[Chills](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:39 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:38:11

[Cough](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:39 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:38:11

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:39 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:38:11

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:39 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:38:11

[Fatigue](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:39 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:38:11

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:39 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:38:11

[Body Aches](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:39 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:38:11

[Headache](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:39 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:38:11

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:39 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:38:11

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:39 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:38:11

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:39 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:38:11

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:39 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:38:11

[Nausea](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:39 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:38:11

[Vomiting](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:39 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:38:11

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:39 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:38:11

[Sore Throat](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:39 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:38:11

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'Day 4 (Day 4)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:52 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:38:11

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered '08 Nov 2020' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:52 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:38:11

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'I' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:52 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:38:11

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:52 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:38:11

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User entered empty. | System | 07 Apr 2021 00:49:52 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:38:11

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:52 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:38:11

[Chills](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:52 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:38:11

[Cough](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:52 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:38:11

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:52 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:38:11

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:52 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:38:11

[Fatigue](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:52 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:38:11

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:52 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:38:11

[Body Aches](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:52 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:38:11

[Headache](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:52 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:38:11

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:52 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:38:11

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:52 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:38:11

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:52 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:38:11

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:52 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:38:11

[Nausea](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:52 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:38:11

[Vomiting](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:52 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:38:11

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:52 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:38:11

[Sore Throat](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:49:52 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:38:11

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'Day 5 (Day 5)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:50:05 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:38:11

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered '09 Nov 2020' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:50:05 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:38:11

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'I' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:50:05 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:38:11

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:50:05 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:38:11

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User entered empty. | System | 07 Apr 2021 00:50:05 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:38:11

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:50:05 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:38:11

[Chills](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:50:05 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:38:11

[Cough](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:50:05 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:38:11

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:50:05 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:38:11

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:50:05 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:38:11

[Fatigue](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:50:05 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:38:11

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:50:05 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:38:11

[Body Aches](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:50:05 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:38:11

[Headache](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:50:05 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:38:11

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:50:05 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:38:11

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:50:05 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:38:11

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:50:05 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:38:11

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:50:05 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:38:11

[Nausea](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:50:05 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:38:11

[Vomiting](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:50:05 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:38:11

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:50:05 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:38:11

[Sore Throat](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:50:05 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:38:11

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'Day 6 (Day 6)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:52:12 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:38:11

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered '10 Nov 2020' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:52:12 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:38:11

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered '0' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:52:12 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:38:11

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered '95' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:52:12 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:38:11

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User entered '%' | System | 07 Apr 2021 00:52:12 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:38:11

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered '99.2' F | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:52:12 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:38:11

[Chills](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'Severe (Severe)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:52:12 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:38:11

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'Mild (Mild)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:52:12 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:38:11

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'Severe (Severe)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:52:12 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:38:11

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'Moderate (Moderate)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:52:12 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:38:11

[Fatigue](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'Severe (Severe)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:52:12 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:38:11

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'Severe (Severe)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:52:12 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:38:11

[Body Aches](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'Severe (Severe)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:52:12 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:38:11

[Headache](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'Severe (Severe)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:52:12 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:38:11

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'None (None)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:52:12 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:38:11

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'None (None)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:52:12 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:38:11

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'None (None)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:52:12 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:38:11

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'None (None)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:52:12 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:38:11

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'None (None)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:52:12 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:38:11

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'None (None)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:52:12 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:38:11

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'None (None)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:52:12 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:38:11

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'None (None)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:52:12 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:38:11

[Date of Visit](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered '10 Nov 2020' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:28:38 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:38:11

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'Yes (Y)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:28:38 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:38:11

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'No (N)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:28:38 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:38:11

[Date of Test](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered '10 Nov 2020' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:28:38 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:38:11

[Type of Test Performed](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:28:38 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:38:11

[Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:28:38 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:38:11

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'No (N)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:28:38 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:38:11

[Lab/ Institution Test Performed](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:28:38 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:38:11

[CLIA Certified?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:28:38 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:38:11

[COVID-19 Positive \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User entered '0' | System | 07 Apr 2021 00:28:38 |

US3192734

Folder: Covid-19 Assessment 10 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:38:11

[Generate Next COVID-19 Assessment](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:27:15 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'No (N)' | Yvonne De Los Reyes (b) (4) | 07 Apr 2021 00:27:38 |

US3192734

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:38:11

[Visit](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User accepted default value 'Day 3 (Day 3)' | Tianna Young (b) (4) (b) (4) | 30 Mar 2021 19:49:15 |

US3192734

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:38:11

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'NA (COVID-19 Negative) (NA)' | (b) (4) Tianna Young (b) (4) | 30 Mar 2021 19:49:15 |
| | (b) (4) | |

US3192734

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:38:11

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| | (b) (4) | |
| User entered empty. | Tianna Young (b) (4) | 30 Mar 2021 19:49:15 |
| | (b) (4) | |

US3192734

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:38:11

[Visit](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User accepted default value 'Day 5 (Day 5)' | Tianna Young (b) (4) (b) (4) | 30 Mar 2021 19:49:15 |

US3192734

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:38:11

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'NA (COVID-19 Negative) (NA)' | (b) (4) Tianna Young (b) (4) | 30 Mar 2021 19:49:15 |
| | (b) (4) | |

US3192734

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:38:11

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) (b) (4) | 03 Apr 2021 14:32:44 |
| User entered empty. | Tianna Young (b) (4) (b) (4) | 30 Mar 2021 19:49:15 |

US3192734

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:38:11

[Visit](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User accepted default value 'Day 7 (Day 7)' | Tianna Young (b) (4) (b) (4) | 30 Mar 2021 19:49:15 |

US3192734

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:38:11

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'NA (COVID-19 Negative) (NA)' | (b) (4) Tianna Young (b) (4) | 30 Mar 2021 19:49:15 |
| | (b) (4) | |

US3192734

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:38:11

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| | (b) (4) | |
| User entered empty. | Tianna Young (b) (4) | 30 Mar 2021 19:49:15 |
| | (b) (4) | |

US3192734

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:38:11

[Visit](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User accepted default value 'Day 9 (Day 9)' | Tianna Young (b) (4) (b) (4) | 30 Mar 2021 19:49:15 |

US3192734

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:38:11

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'NA (COVID-19 Negative) (NA)' | (b) (4) Tianna Young (b) (4) | 30 Mar 2021 19:49:15 |
| | (b) (4) | |

US3192734

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:38:11

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) (b) (4) | 03 Apr 2021 14:32:44 |
| User entered empty. | Tianna Young (b) (4) (b) (4) | 30 Mar 2021 19:49:15 |

US3192734

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:38:11

[Visit](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User accepted default value 'Day 14 (Day 14)' | Tianna Young (b) (4) (b) (4) | 30 Mar 2021 19:49:15 |

US3192734

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:38:11

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'NA (COVID-19 Negative) (NA)' | (b) (4) Tianna Young (b) (4) | 30 Mar 2021 19:49:15 |
| | (b) (4) | |

US3192734

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:38:11

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| | (b) (4) | |
| User entered empty. | Tianna Young (b) (4) | 30 Mar 2021 19:49:15 |
| | (b) (4) | |

US3192734

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:38:11

[Visit](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User accepted default value 'Day 21 (Day 21)' | Tianna Young (b) (4) (b) (4) | 30 Mar 2021 19:49:15 |

US3192734

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:38:11

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'NA (COVID-19 Negative) (NA)' | (b) (4) Tianna Young (b) (4) | 30 Mar 2021 19:49:15 |
| | (b) (4) | |

US3192734

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:38:11

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| | (b) (4) | |
| User entered empty. | Tianna Young (b) (4) | 30 Mar 2021 19:49:15 |
| | (b) (4) | |

US3192734

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:38:11

[Visit](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User accepted default value 'Day 28 (Day 28)' | Tianna Young (b) (4) (b) (4) | 30 Mar 2021 19:49:15 |

US3192734

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:38:11

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'NA (COVID-19 Negative) (NA)' | (b) (4) Tianna Young (b) (4) | 30 Mar 2021 19:49:15 |
| | (b) (4) | |

US3192734

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:38:11

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| | (b) (4) | |
| User entered empty. | Tianna Young (b) (4) | 30 Mar 2021 19:49:15 |
| | (b) (4) | |

US3192734

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:11

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:10:55 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'Yes (Y)' | Zoe Sesma (b) (4) | 11 Nov 2020 01:37:08 |

US3192734

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:11

Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:10:55 |
| User closed query 'Per GCL Lab Reconciliation: Swab: Per response, since an additional swab was collected and in EDC, additional swab can be recorded only under COVID-19 Assessment visit- COVID diagnostic form. Please review and initiate a COVID-19 Assessment visit and record the 10NOV2020 swab under COVID Diagnostic form. Thank you.' (Site from DM). User signature succeeded. | (b) (4) | 12 Apr 2021 11:44:36 |
| Query 'Per GCL Lab Reconciliation: Swab: Per response, since an additional swab was collected and in EDC, additional swab can be recorded only under COVID-19 Assessment visit- COVID diagnostic form. Please review and initiate a COVID-19 Assessment visit and record the 10NOV2020 swab under COVID Diagnostic form. Thank you.' answered with 'Updated' (Site from DM). | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User opened query 'Per GCL Lab Reconciliation: Swab: Per response, since an additional swab was collected and in EDC, additional swab can be recorded only under COVID-19 Assessment visit- COVID diagnostic form. Please review and initiate a COVID-19 Assessment visit and record the 10NOV2020 swab under COVID Diagnostic form. Thank you.' (Site from DM). | (b) (4) | |
| User closed query 'Per GCL Lab Reconciliation: Central Laboratory - Nasopharyngeal Swab: Sample Collection Date 10NOV2020 is reported under Illness Visit Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review and update the details under appropriate visit. Else clarify, thank you.' (Site from DM). | Tianna Young (b) (4) | 07 Apr 2021 15:22:00 |
| | (b) (4) | |
| | (b) (4), (b) (6) | 25 Jan 2021 06:55:09 |
| | | 25 Jan 2021 06:55:09 |

US3192734

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:11

Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Query 'Per GCL Lab Reconciliation: Central Laboratory - Nasopharyngeal Swab: Sample Collection Date 10NOV2020 is reported under Illness Visit Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review and update the details under appropriate visit. Else clarify, thank you.' answered with 'THERE ARE NO ECRFS TO ENTER THIS DATA UNDER ILLNESS VISIT DAY 1. PLEASE ADVISE.' (Site from DM). | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 20:16:04 |
| User opened query 'Per GCL Lab Reconciliation: Central Laboratory - Nasopharyngeal Swab: Sample Collection Date 10NOV2020 is reported under Illness Visit Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review and update the details under appropriate visit. Else clarify, thank you.' (Site from DM). | (b) (4), (b) (6) (b) (4) | 18 Nov 2020 07:20:26 |
| User entered '10 Nov 2020' | Zoe Sesma (b) (4) (b) (4) | 11 Nov 2020 01:37:08 |

US3192734

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:10:55 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 01:46:37 |
| User entered 'Clinic (Clinic)' | Zoe Sesma (b) (4) | 11 Nov 2020 01:37:08 |

US3192734

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:11

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:10:55 |
| User entered 'SICKD1' | System | 11 Nov 2020 01:37:08 |

US3192734

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:10:55 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Yes (Y)' | Zoe Sesma (b) (4) | 11 Nov 2020 01:37:48 |

US3192734

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:10:55 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '10 Nov 2020' | Zoe Sesma (b) (4) | 11 Nov 2020 01:37:48 |

US3192734

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:10:55 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '13:43' | Zoe Sesma (b) (4) | 11 Nov 2020 01:37:48 |

US3192734

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:10:55 |
| User entered '10 Nov 2020 13:43' | System | 11 Nov 2020 01:37:48 |

US3192734

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:10:55 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered missing code ND - Not Done. | Zoe Sesma (b) (4) | 11 Nov 2020 01:37:48 |
| DataPoint set to visible. | System | 11 Nov 2020 01:37:08 |

US3192734

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:10:55 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered missing code ND - Not Done. | Zoe Sesma (b) (4) | 11 Nov 2020 01:37:48 |
| DataPoint set to visible. | System | 11 Nov 2020 01:37:08 |

US3192734

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:10:55 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '99.2' F | Zoe Sesma (b) (4) | 11 Nov 2020 01:37:48 |

US3192734

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:10:55 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Oral (Oral)' | Zoe Sesma (b) (4) | 11 Nov 2020 01:37:48 |

US3192734

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:10:55 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered empty. | Zoe Sesma (b) (4) | 11 Nov 2020 01:37:48 |

US3192734

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:10:55 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '97' | Zoe Sesma (b) (4) | 11 Nov 2020 01:37:48 |

US3192734

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:10:55 |
| User entered 'bpm' | System | 11 Nov 2020 01:37:48 |

US3192734

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:10:55 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '20' | Zoe Sesma (b) (4) | 11 Nov 2020 01:37:48 |

US3192734

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:10:55 |
| User entered 'breaths/min' | System | 11 Nov 2020 01:37:48 |

US3192734

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:10:55 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '120' | Zoe Sesma (b) (4) | 11 Nov 2020 01:37:48 |

US3192734

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:10:55 |
| User entered 'mmHg' | System | 11 Nov 2020 01:37:48 |

US3192734

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:10:55 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '80' | Zoe Sesma (b) (4) | 11 Nov 2020 01:37:48 |

US3192734

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:10:55 |
| User entered 'mmHg' | System | 11 Nov 2020 01:37:48 |

US3192734

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:10:55 |
| | | |

US3192734

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Weight \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:10:55 |
| | | |

US3192734

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:38:11

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:10:55 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Yes (Y)' | Zoe Sesma (b) (4) | 11 Nov 2020 01:37:54 |

US3192734

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:38:11

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:10:55 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '10 Nov 2020' | Zoe Sesma (b) (4) | 11 Nov 2020 01:37:54 |

US3192734

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 15:38:11

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:10:55 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Yes (Y)' | Zoe Sesma (b) (4) | 11 Nov 2020 01:38:04 |

US3192734

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 15:38:11

[Date of Collection](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 18:10:55 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '10 Nov 2020' | Zoe Sesma (b) (4) | 11 Nov 2020 01:38:04 |

US3192734

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:11

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| | (b) (4) | |
| User entered 'No (N)' | Tianna Young (b) (4) | 30 Mar 2021 19:49:02 |
| | (b) (4) | |

US3192734

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| | (b) (4) | |
| User entered empty. | Tianna Young (b) (4) | 30 Mar 2021 19:49:02 |
| | (b) (4) | |

US3192734

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| | (b) (4) | |
| User entered empty. | Tianna Young (b) (4) | 30 Mar 2021 19:49:02 |
| | (b) (4) | |

US3192734

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:11

[Folder OID](#)

| Audit | User | Time (GMT) |
|------------------------|--------|----------------------|
| User entered 'SICKD28' | System | 30 Mar 2021 19:49:02 |

US3192734

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| | (b) (4) | |
| User entered 'No (N)' | Tianna Young (b) (4) | 30 Mar 2021 19:48:52 |
| | (b) (4) | |

US3192734

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) (b) (4) | 03 Apr 2021 14:32:44 |
| User entered empty. | Tianna Young (b) (4) (b) (4) | 30 Mar 2021 19:48:52 |

US3192734

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| | (b) (4) | |
| User entered empty. | Tianna Young (b) (4) | 30 Mar 2021 19:48:52 |
| | (b) (4) | |

US3192734

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 30 Mar 2021 19:48:52 |

US3192734

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| | (b) (4) | |
| User entered empty. | Tianna Young (b) (4) | 30 Mar 2021 19:48:52 |
| | (b) (4) | |

US3192734

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| | (b) (4) | |
| User entered empty. | Tianna Young (b) (4) | 30 Mar 2021 19:48:52 |
| | (b) (4) | |

US3192734

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| | (b) (4) | |
| User entered empty. | Tianna Young (b) (4) | 30 Mar 2021 19:48:52 |
| | (b) (4) | |

US3192734

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| | (b) (4) | |
| User entered empty. | Tianna Young (b) (4) | 30 Mar 2021 19:48:52 |
| | (b) (4) | |

US3192734

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 30 Mar 2021 19:48:52 |

US3192734

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| | (b) (4) | |
| User entered empty. | Tianna Young (b) (4) | 30 Mar 2021 19:48:52 |
| | (b) (4) | |

US3192734

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 30 Mar 2021 19:48:52 |

US3192734

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered empty. | (b) (4) Tianna Young (b) (4) | 30 Mar 2021 19:48:52 |
| | (b) (4) | |

US3192734

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 30 Mar 2021 19:48:52 |

US3192734

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered empty. | (b) (4) Tianna Young (b) (4) | 30 Mar 2021 19:48:52 |
| | (b) (4) | |

US3192734

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 30 Mar 2021 19:48:52 |

US3192734

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:38:11

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| | (b) (4) | |
| User entered 'No (N)' | Tianna Young (b) (4) | 30 Mar 2021 19:48:56 |
| | (b) (4) | |

US3192734

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:38:11

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| | (b) (4) | |
| User entered empty. | Tianna Young (b) (4) | 30 Mar 2021 19:48:56 |
| | (b) (4) | |

US3192734

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 15:38:11

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'NA (COVID-19 Negative) (NA)' | (b) (4) Tianna Young (b) (4) | 30 Mar 2021 19:49:06 |
| | (b) (4) | |

US3192734

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 15:38:11

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| | (b) (4) | |
| User entered empty. | Tianna Young (b) (4) | 30 Mar 2021 19:49:06 |
| | (b) (4) | |

US3192734

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

Form: Visit Date

Generated On: 09 Jun 2021 15:38:11

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:56:58 |

US3192734

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

Form: Visit Date

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '30 Jan 2021' | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:56:58 |

US3192734

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

Form: Visit Date

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:56:58 |

US3192734

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

Form: Visit Date

Generated On: 09 Jun 2021 15:38:11

[Folder OID](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User entered 'UNBLND_DECIDE' | System | 31 Jan 2021 00:56:58 |

US3192734

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

Form: Unblinding

Generated On: 09 Jun 2021 15:38:11

[Date of updated informed consent \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '30 Jan 2021' | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:57:11 |

US3192734

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

Form: Unblinding

Generated On: 09 Jun 2021 15:38:11

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 12 Apr 2021 18:02:51 |
| User entered '0' | (b) (4) | |
| | Amanda Hermosillo | 09 Apr 2021 21:08:09 |
| Amendment Manager inserted this DataPoint. | (b) (4) | |
| | System | 06 Mar 2021 15:22:49 |

US3192734

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

Form: Unblinding

Generated On: 09 Jun 2021 15:38:11

[Was the participant unblinded?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:57:11 |

US3192734

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

Form: Unblinding

Generated On: 09 Jun 2021 15:38:11

[Under what version of the Protocol was the Participant unblinded?](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM). | | 16 Apr 2021 04:26:02 |
| User signature succeeded. | John McGettigan (b) (4) | 12 Apr 2021 18:02:51 |
| Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM). | (b) (4) | |
| | Amanda Hermosillo | 09 Apr 2021 21:08:24 |
| | (b) (4) | |
| User entered 'Amendment 6 or later (Amendment 6 or later)' | Amanda Hermosillo | 09 Apr 2021 21:08:09 |
| | (b) (4) | |
| User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM). | (b) (4), (b) (6) | 09 Apr 2021 19:13:58 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 15:22:49 |

US3192734

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

Form: Unblinding

Generated On: 09 Jun 2021 15:38:11

Date of unblinding (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '30 Jan 2021' | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:57:11 |

US3192734

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

Form: Unblinding

Generated On: 09 Jun 2021 15:38:11

[Participant randomization assignment](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Placebo (Placebo)' | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:57:11 |

US3192734

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

Form: Unblinding

Generated On: 09 Jun 2021 15:38:11

[Actual Dose 1](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Placebo (Placebo)' | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:57:11 |

US3192734

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

Form: Unblinding

Generated On: 09 Jun 2021 15:38:11

[Actual Dose 2](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Placebo (Placebo)' | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:57:11 |

US3192734

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

Form: Unblinding

Generated On: 09 Jun 2021 15:38:11

[Will participant receive mRNA-1273?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:57:11 |

US3192734

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

Form: Unblinding

Generated On: 09 Jun 2021 15:38:11

[Placebo Only Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User entered '1' | System | 31 Jan 2021 00:57:11 |

US3192734

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

Form: Unblinding

Generated On: 09 Jun 2021 15:38:11

[Continuing with mRNA-1273](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User entered 'I' | System | 31 Jan 2021 00:57:11 |

US3192734

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:38:11

[Height](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:59:19 |

US3192734

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:38:11

[Weight](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:59:19 |

US3192734

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:38:11

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User entered empty. | System | 31 Jan 2021 00:59:19 |
| DataPoint set to visible. | System | 31 Jan 2021 00:57:11 |

US3192734

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:38:11

[Height](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:59:19 |

US3192734

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:38:11

[Weight](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:59:19 |

US3192734

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:38:11

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User entered empty. | System | 31 Jan 2021 00:59:19 |
| DataPoint set to visible. | System | 31 Jan 2021 00:57:11 |

US3192734

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User accepted default value 'Pre-Dose (PREDOSE)' | | 31 Jan 2021 00:59:19 |

US3192734

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:59:19 |

US3192734

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '30 Jan 2021' | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:59:19 |

US3192734

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '13:48' | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:59:19 |

US3192734

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User entered '30 Jan 2021 13:48' | System | 31 Jan 2021 00:59:19 |

US3192734

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| 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) (4), (b) (6) | 19 Feb 2021 06:17:46 |
| 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 'Not clinically significant ' (Site from System). | (b) (4), (b) (6) | 31 Jan 2021 01:00:14 |
| 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 | 31 Jan 2021 00:59:19 |
| User entered '96.5' F | (b) (4), (b) (6) | 31 Jan 2021 00:59:19 |

US3192734

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Oral (Oral)' | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:59:19 |

US3192734

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:59:19 |

US3192734

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '66' | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:59:19 |

US3192734

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User entered 'bpm' | System | 31 Jan 2021 00:59:19 |

US3192734

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '16' | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:59:19 |

US3192734

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User entered 'breaths/min' | System | 31 Jan 2021 00:59:19 |

US3192734

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '132' | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:59:19 |

US3192734

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User entered 'mmHg' | System | 31 Jan 2021 00:59:19 |

US3192734

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '85' | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:59:19 |

US3192734

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User entered 'mmHg' | System | 31 Jan 2021 00:59:19 |

US3192734

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:38:11

[Height](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:59:19 |

US3192734

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:38:11

[Weight](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:59:19 |

US3192734

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:38:11

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User entered empty. | System | 31 Jan 2021 00:59:19 |
| DataPoint set to visible. | System | 31 Jan 2021 00:57:11 |

US3192734

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User accepted default value 'Post-Dose (POSTDOSE)' | | 31 Jan 2021 00:59:19 |

US3192734

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:59:19 |

US3192734

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '30 Jan 2021' | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:59:19 |

US3192734

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '15:08' | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:59:19 |

US3192734

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User entered '30 Jan 2021 15:08' | System | 31 Jan 2021 00:59:19 |

US3192734

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '97.6' F | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:59:19 |

US3192734

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Oral (Oral)' | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:59:19 |

US3192734

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:59:19 |

US3192734

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '72' | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:59:19 |

US3192734

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User entered 'bpm' | System | 31 Jan 2021 00:59:19 |

US3192734

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '14' | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:59:19 |

US3192734

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User entered 'breaths/min' | System | 31 Jan 2021 00:59:19 |

US3192734

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '126' | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:59:19 |

US3192734

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User entered 'mmHg' | System | 31 Jan 2021 00:59:19 |

US3192734

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '87' | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:59:19 |

US3192734

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User entered 'mmHg' | System | 31 Jan 2021 00:59:19 |

US3192734

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:38:11

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 01:00:22 |

US3192734

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:38:11

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '30 Jan 2021' | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 01:00:22 |

US3192734

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

Form: Exposure

Generated On: 09 Jun 2021 15:38:11

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:57:47 |

US3192734

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

Form: Exposure

Generated On: 09 Jun 2021 15:38:11

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:57:47 |

US3192734

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

Form: Exposure

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:57:47 |

US3192734

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

Form: Exposure

Generated On: 09 Jun 2021 15:38:11

[What was the study treatment? \(Unblinded\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User entered 'mRNA-1273' | System | 31 Jan 2021 00:57:47 |
| DataPoint set to visible. | System | 31 Jan 2021 00:57:11 |

US3192734

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

Form: Exposure

Generated On: 09 Jun 2021 15:38:11

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '30 Jan 2021' | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:57:47 |

US3192734

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

Form: Exposure

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '14:38' | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:57:47 |

US3192734

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

Form: Exposure

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User entered '30 Jan 2021 14:38' | System | 31 Jan 2021 00:57:47 |

US3192734

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

Form: Exposure

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:57:47 |

US3192734

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

Form: Exposure

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User entered 'ONCE' | System | 31 Jan 2021 00:57:47 |

US3192734

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

Form: Exposure

Generated On: 09 Jun 2021 15:38:11

[What was the route of administration for the study treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User entered 'INTRAMUSCULAR' | System | 31 Jan 2021 00:57:47 |

US3192734

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:11

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:57:21 |

US3192734

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:11

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '30 Jan 2021' | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:57:21 |

US3192734

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:11

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '14:00' | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:57:21 |

US3192734

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User entered '30 Jan 2021 14:00' | System | 31 Jan 2021 00:57:21 |

US3192734

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:38:11

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:57:31 |

US3192734

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:38:11

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '30 Jan 2021' | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:57:31 |

US3192734

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:38:11

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '14:05' | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:57:31 |

US3192734

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:38:11

[Collection Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User entered '30 Jan 2021 14:05' | System | 31 Jan 2021 00:57:31 |

US3192734

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:11

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 31 Jan 2021 00:57:34 |

US3192734

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:11

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User entered 'I' | System | 31 Jan 2021 00:57:34 |

US3192734

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 17 Feb 2021 23:06:08 |

US3192734

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '9 Feb 2021' | (b) (4) (b) (4), (b) (6) | 17 Feb 2021 23:06:08 |

US3192734

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 17 Feb 2021 23:06:08 |

US3192734

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 17 Feb 2021 23:06:08 |

US3192734

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:11

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 17 Feb 2021 23:06:13 |

US3192734

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:11

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User entered 'I' | System | 17 Feb 2021 23:06:13 |

US3192734

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:11

[OLD29 Placebo Flag](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User entered '1' | System | 17 Feb 2021 23:06:13 |
| DataPoint set to visible. | System | 17 Feb 2021 23:06:13 |

US3192734

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:11

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 21:47:49 |

US3192734

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:11

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '1 Mar 2021' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 21:47:49 |

US3192734

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:11

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 21:47:49 |

US3192734

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:11

[Folder OID](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User entered 'OLD29' | System | 01 Mar 2021 21:47:49 |

US3192734

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User accepted default value 'Pre-Dose (PREDOSE)' | | 01 Mar 2021 21:48:41 |

US3192734

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 21:48:41 |

US3192734

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '1 Mar 2021' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 21:48:41 |

US3192734

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '14:20' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 21:48:41 |

US3192734

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User entered '1 Mar 2021 14:20' | System | 01 Mar 2021 21:48:41 |

US3192734

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

[Temperature \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '97.9' F | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 21:48:41 |

US3192734

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Oral (Oral)' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 21:48:41 |

US3192734

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 21:48:41 |

US3192734

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '80' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 21:48:41 |

US3192734

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User entered 'bpm' | System | 01 Mar 2021 21:48:41 |

US3192734

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '12' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 21:48:41 |

US3192734

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User entered 'breaths/min' | System | 01 Mar 2021 21:48:41 |

US3192734

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '112' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 21:48:41 |

US3192734

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User entered 'mmHg' | System | 01 Mar 2021 21:48:41 |

US3192734

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '75' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 21:48:41 |

US3192734

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:11

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User entered 'mmHg' | System | 01 Mar 2021 21:48:41 |

US3192734

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User accepted default value 'Post-Dose (POSTDOSE)' | | 01 Mar 2021 22:24:22 |

US3192734

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 22:24:22 |

US3192734

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '1 Mar 2021' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 22:24:22 |

US3192734

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '15:08' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 22:24:22 |

US3192734

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User entered '1 Mar 2021 15:08' | System | 01 Mar 2021 22:24:22 |

US3192734

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

[Temperature \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '98.1' F | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 22:24:22 |

US3192734

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Oral (Oral)' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 22:24:22 |

US3192734

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 22:24:22 |

US3192734

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '84' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 22:24:22 |

US3192734

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User entered 'bpm' | System | 01 Mar 2021 22:24:22 |

US3192734

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '14' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 22:24:22 |

US3192734

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User entered 'breaths/min' | System | 01 Mar 2021 22:24:22 |

US3192734

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '113' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 22:24:22 |

US3192734

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User entered 'mmHg' | System | 01 Mar 2021 22:24:22 |

US3192734

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '82' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 22:24:22 |

US3192734

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:11

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User entered 'mmHg' | System | 01 Mar 2021 22:24:22 |

US3192734

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:38:11

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 21:49:00 |

US3192734

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:38:11

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '1 Mar 2021' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 21:49:00 |

US3192734

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:11

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 21:49:24 |

US3192734

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:11

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 21:49:24 |

US3192734

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:11

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 21:49:24 |

US3192734

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:11

[What was the study treatment? \(Unblinded\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User entered 'mRNA-1273' | System | 01 Mar 2021 21:49:24 |
| DataPoint set to visible. | System | 17 Feb 2021 23:06:13 |

US3192734

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:11

[What was the treatment date? \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '1 Mar 2021' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 21:49:24 |

US3192734

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:11

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '14:38' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 21:49:24 |

US3192734

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:11

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User entered '1 Mar 2021 14:38' | System | 01 Mar 2021 21:49:24 |

US3192734

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:11

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 21:49:24 |

US3192734

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:11

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User entered 'ONCE' | System | 01 Mar 2021 21:49:24 |

US3192734

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:11

[What was the route of administration for the study treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User entered 'INTRAMUSCULAR' | System | 01 Mar 2021 21:49:24 |

US3192734

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:11

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 21:49:29 |

US3192734

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:11

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User entered 'I' | System | 01 Mar 2021 21:49:29 |

US3192734

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Yes (Y)' | Damaris Atondo (b) (4) | 14 Mar 2021 21:27:13 |

US3192734

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '8 Mar 2021' | Damaris Atondo (b) (4) | 14 Mar 2021 21:27:13 |

US3192734

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Contact Made (CONTACT MADE)' | Damaris Atondo (b) (4) | 14 Mar 2021 21:27:13 |

US3192734

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:11

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered empty. | Damaris Atondo (b) (4) | 14 Mar 2021 21:27:13 |

US3192734

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:11

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Yes (Y)' | Damaris Atondo (b) (4) | 14 Mar 2021 21:27:20 |

US3192734

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:11

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:44:36 |
| User entered 'I' | System | 14 Mar 2021 21:27:20 |

US3192734

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:11

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 15:50:28 |

US3192734

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:11

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '2 Apr 2021' | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 15:50:28 |

US3192734

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:11

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 15:50:28 |

US3192734

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:11

[Folder OID](#)

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| User entered 'OLD57' | System | 02 Apr 2021 15:50:28 |

US3192734

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 15:51:19 |

US3192734

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '2 Apr 2021' | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 15:51:19 |

US3192734

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '08:36' | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 15:51:19 |

US3192734

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|--------|----------------------|
| User entered '2 Apr 2021 08:36' | System | 02 Apr 2021 15:51:19 |

US3192734

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '97.2' F | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 15:51:19 |

US3192734

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Oral (Oral)' | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 15:51:19 |

US3192734

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 15:51:19 |

US3192734

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '61' | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 15:51:19 |

US3192734

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 02 Apr 2021 15:51:19 |

US3192734

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '12' | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 15:51:19 |

US3192734

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 02 Apr 2021 15:51:19 |

US3192734

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '144' | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 15:51:19 |

US3192734

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 02 Apr 2021 15:51:19 |

US3192734

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '91' | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 15:51:19 |

US3192734

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:11

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 02 Apr 2021 15:51:19 |

US3192734

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:38:11

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 15:51:27 |

US3192734

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:38:11

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 15:51:27 |

US3192734

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:11

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 15:51:44 |

US3192734

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:11

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '2 Apr 2021' | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 15:51:44 |

US3192734

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:11

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '08:47' | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 15:51:44 |

US3192734

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:11

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|--------|----------------------|
| User entered '2 Apr 2021 08:47' | System | 02 Apr 2021 15:51:44 |

US3192734

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:38:11

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 16:54:10 |
| User signature succeeded. | John McGettigan (b) (4) | 28 Mar 2021 18:41:43 |
| User closed query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of JOINT ACHES persist beyond Day 7 (start date: Day 4; end date: Day 15). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 22 Mar 2021 10:31:10 |
| Query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of JOINT ACHES persist beyond Day 7 (start date: Day 4; end date: Day 15). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'updated ' (Site from DM). | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:27:41 |
| User opened query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of JOINT ACHES persist beyond Day 7 (start date: Day 4; end date: Day 15). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM). | (b) (4), (b) (6) | 27 Feb 2021 08:37:15 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 17:47:03 |
| User entered 'No (N)' reason for change: Data Entry Error | Tianna Young (b) (4) (b) (4) | 02 Dec 2020 22:07:19 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Tianna Young (b) (4) (b) (4) | 02 Dec 2020 21:48:52 |
| User entered 'No (N)' | Yvonne De Los Reyes (b) (4) | 09 Oct 2020 23:21:17 |

US3192734

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:11

[AEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 17 Mar 2021 14:57:45 |
| User entered 'USA-US097-2021-mRNA-1273-P301000006' | System | 25 Jan 2021 17:47:56 |
| User entered 'New' | (b) (4), (b) (6) | 25 Jan 2021 17:47:56 |

US3192734

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:11

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) | 28 Jan 2021 16:32:22 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 28 Jan 2021 16:32:22 |
| Data point term sent to Coder | System | 23 Jan 2021 17:58:39 |
| Coding entries removed. | Crystal Mata (b) (4) | 23 Jan 2021 17:57:48 |
| User entered 'RLL PNEUMONIA' reason for change: Data Entry Error | (b) (4) | |
| User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\\23.0. | Crystal Mata (b) (4) | 23 Jan 2021 17:57:48 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | (b) (4) | |
| Data point term sent to Coder | Coder Import (b) (4) | 23 Jan 2021 17:53:02 |
| User entered 'PNEUMONIA' | (b) (4) | |
| | System | 23 Jan 2021 17:52:37 |
| | Crystal Mata (b) (4) | 23 Jan 2021 17:52:13 |
| | (b) (4) | |

US3192734

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:11

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Yes (Y)' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 17:52:13 |

US3192734

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:11

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 17:52:13 |

US3192734

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 17:52:13 |

US3192734

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:11

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered '18 Nov 2020' reason for change: Data Entry Error | Crystal Mata (b) (4) | 23 Jan 2021 17:57:48 |
| | (b) (4) | |
| User entered '14 Nov 2020' | Crystal Mata (b) (4) | 23 Jan 2021 17:52:13 |
| | (b) (4) | |

US3192734

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:11

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 17:52:13 |

US3192734

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:11

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 23 Jan 2021 17:52:13 |

US3192734

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:11

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 17:52:13 |

US3192734

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:11

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered '25 Nov 2020' reason for change: Data Entry Error | Crystal Mata (b) (4) | 23 Jan 2021 17:57:48 |
| | (b) (4) | |
| User entered '23 Nov 2020' | Crystal Mata (b) (4) | 23 Jan 2021 17:52:13 |
| | (b) (4) | |

US3192734

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:11

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 17:52:13 |

US3192734

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:11

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 23 Jan 2021 17:52:13 |

US3192734

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:11

[Severity](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| Query 'PV Query: Since the subject was hospitalized for the event of RLL pneumonia and cough with difficulty breathing, appropriate CTCAE grade should be grade 3 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain. ' canceled (Site from Safety). | (b) (4) (D) (4), (b) (6) | 01 Mar 2021 18:16:40 |
| User opened query 'PV Query: Since the subject was hospitalized for the event of RLL pneumonia and cough with difficulty breathing, appropriate CTCAE grade should be grade 3 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain. ' (Site from Safety). | | 01 Feb 2021 19:57:30 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 17:52:13 |

US3192734

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:11

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System). | (b) (4) System | 23 Jan 2021 18:04:45 |
| User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System). | System | 23 Jan 2021 17:57:48 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 17:57:48 |
| User entered 'No (N)' | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 17:52:13 |

US3192734

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:11

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 17:52:13 |

US3192734

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:11

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 17:52:13 |

US3192734

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:11

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '1' reason for change: Data Entry Error | (b) (4) Crystal Mata (b) (4) | 23 Jan 2021 18:04:45 |
| User entered '0' | (b) (4) Crystal Mata (b) (4) | 23 Jan 2021 17:52:13 |

US3192734

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:11

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered '18 Nov 2020' reason for change: Data Entry Error | Crystal Mata (b) (4) | 23 Jan 2021 18:04:45 |
| | (b) (4) | |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 17:52:13 |
| | (b) (4) | |

US3192734

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:11

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered '25 Nov 2020' reason for change: Data Entry Error | Crystal Mata (b) (4) | 23 Jan 2021 18:04:45 |
| | (b) (4) | |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 17:52:13 |
| | (b) (4) | |

US3192734

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:11

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System). | (b) (4) System | 23 Jan 2021 18:14:09 |
| Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System). | | 23 Jan 2021 18:14:09 |
| User entered 'No (N)' reason for change: Data Entry Error | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:14:09 |
| User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System). | System | 23 Jan 2021 18:04:45 |
| User entered 'Unknown (UNK)' reason for change: Data Entry Error | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:04:45 |
| User entered empty. | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 17:52:13 |

US3192734

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:11

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 17:52:13 |

US3192734

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:11

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 17:52:13 |

US3192734

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:11

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 17:52:13 |

US3192734

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:11

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 17:52:13 |

US3192734

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:11

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 23 Jan 2021 17:53:49 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 23 Jan 2021 17:53:49 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error | Crystal Mata (b) (4) | 23 Jan 2021 17:53:49 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 23 Jan 2021 17:52:13 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 17:52:13 |
| | (b) (4) | |

US3192734

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:11

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 23 Jan 2021 17:53:49 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 23 Jan 2021 17:53:49 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error | Crystal Mata (b) (4) | 23 Jan 2021 17:53:49 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 23 Jan 2021 17:52:13 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 17:52:13 |
| | (b) (4) | |

US3192734

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:11

Action taken with investigational product

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User closed query 'PV Query: As the last dose of study drug was given on 02 Nov 2020, please consider updating the action taken with study drug from none to not applicable. ' (Site from Safety). | (b) (4) (b) (4), (b) (6) | 17 Mar 2021 14:57:33 |
| Query 'PV Query: As the last dose of study drug was given on 02 Nov 2020, please consider updating the action taken with study drug from none to not applicable. ' answered with 'updated ' (Site from Safety). | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:30:57 |
| User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:30:51 |
| User opened query 'PV Query: As the last dose of study drug was given on 02 Nov 2020, please consider updating the action taken with study drug from none to not applicable. ' (Site from Safety). | (b) (4), (b) (6) | 01 Feb 2021 19:58:13 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 23 Jan 2021 17:53:49 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 23 Jan 2021 17:53:49 |
| User entered 'None (NONE)' reason for change: Data Entry Error | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 17:53:49 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 23 Jan 2021 17:52:13 |
| User entered empty. | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 17:52:13 |

US3192734

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:11

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 17:52:13 |

US3192734

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:11

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '1' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 17:52:13 |

US3192734

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:11

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 17:52:13 |

US3192734

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:11

[Outcome](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 17:52:13 |

US3192734

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:11

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 17:52:13 |

US3192734

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:11

[Narrative](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If no results are available, please confirm in your response. Please leave query open until information is available.' (Site from Safety). | (b) (4), (b) (6) | 03 May 2021 22:11:35 |
| User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If no results are available, please confirm in your response.' (Site from Safety). | | 03 May 2021 22:11:27 |
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If no results are available, please confirm in your response.' answered with 'no results are available yet.' (Site from Safety). | | 30 Apr 2021 16:45:02 |
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If no results are available, please confirm in your response.' (Site from Safety). | | 16 Apr 2021 13:29:01 |
| User closed query 'Per DM CLR: Narrative = PREVIOUS RADIATION. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM). | | 12 Apr 2021 11:07:46 |
| User closed query '. PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If no results are available, please confirm in your response.' (Site from Safety). | | 09 Apr 2021 13:57:34 |
| User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety). | | 09 Apr 2021 13:57:29 |
| User signature succeeded. | John McGettigan (b) (4) (b) (4) | 08 Apr 2021 12:37:15 |

US3192734

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:11

[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. If no results are available, please confirm in your response. ' answered with 'site had made multiple attempts to obtain records, will continue with efforts ' (Site from Safety). | Yvonne De Los Reyes (b) (4) | 08 Apr 2021 02:52:40 |
| Query 'Per DM CLR: Narrative = PREVIOUS RADIATION. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate. ' answered with 'updated ' (Site from DM). | Yvonne De Los Reyes (b) (4) | 08 Apr 2021 02:52:36 |
| Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' answered with 'site had made multiple attempts to obtain records, will continue with efforts ' (Site from Safety). | Yvonne De Los Reyes (b) (4) | 08 Apr 2021 02:51:54 |
| User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' (Site from Safety). | (b) (4), (b) (6) | 17 Mar 2021 14:57:40 |
| User closed query 'PV Query: Please confirm if scar tissue, chronic pulmonary fibrosis, and radiation treatment should be added to medical history. ' (Site from Safety). | | 17 Mar 2021 14:57:38 |
| User closed query 'Per DM CLR: Narrative = PATIENT HAS CHRONIC PULMONARY FIBROSIS. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM). | | 17 Mar 2021 06:21:44 |

US3192734

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:11

[Narrative](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Query 'Per DM CLR: Narrative = PATIENT HAS CHRONIC PULMONARY FIBROSIS. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' answered with 'updated ' (Site from DM). | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:40:19 |
| Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' answered with 'no covid test was done ' (Site from Safety). | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:38:19 |
| Query 'PV Query: Please confirm if scar tissue, chronic pulmonary fibrosis, and radiation treatment should be added to medical history. ' answered with 'updated ' (Site from Safety). | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:37:21 |
| User opened query 'Per DM CLR: Narrative = PATIENT HAS CHRONIC PULMONARY FIBROSIS. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM). | (b) (4), (b) (6) | 20 Feb 2021 22:20:34 |
| User opened query 'Per DM CLR: Narrative = PREVIOUS RADIATION. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate. ' (Site from DM). | | 20 Feb 2021 22:20:27 |
| User opened query '. PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If no results are available, please confirm in your response. ' (Site from Safety). | | 01 Feb 2021 19:59:07 |
| User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety). | | 01 Feb 2021 19:58:41 |
| | | |

US3192734

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:11

[Narrative](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' (Site from Safety). | (b) (4), (b) (6) | 01 Feb 2021 19:58:30 |
| User opened query 'PV Query: Please confirm if scar tissue, chronic pulmonary fibrosis, and radiation treatment should be added to medical history. ' (Site from Safety). | | 01 Feb 2021 19:57:50 |
| User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System). | System | 23 Jan 2021 18:13:57 |
| Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System). | System | 23 Jan 2021 18:13:57 |
| User entered 'Per PI note, on 11/18/2020, husband reported patient looked dazed, called 911 and was admitted. Patient received IV abx (vancomycin, metronidazole, cephalosporin) and oxygen. Patient was discharged from hospital on 11/25/2020 with oxygen and diagnosed with valley fever and scar tissue from previous radiation. Patient has chronic pulmonary fibrosis due to radiation treatment for history of Hodgkin's lymphoma in 1999. Per PI, this SAE is not related to investigational vaccine.' reason for change: Data Entry Error | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:13:57 |
| User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System). | System | 23 Jan 2021 17:57:48 |
| User entered empty. | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 17:52:13 |

US3192734

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:11

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 23 Jan 2021 17:57:48 |
| User entered '0' | System | 23 Jan 2021 17:52:13 |

US3192734

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 23 Jan 2021 17:52:13 |

US3192734

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:11

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 23 Jan 2021 18:04:45 |

US3192734

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:38:11

[AEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 17 Mar 2021 14:57:45 |
| User entered 'USA-US097-2021-mRNA-1273-P301000006' | | 25 Jan 2021 17:48:33 |

US3192734

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:38:11

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Conditions associated with abnormal gas exchange, PT: Hypoxia, LLT: Hypoxia - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) | 26 Jan 2021 12:54:16 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 26 Jan 2021 12:54:16 |
| Data point term sent to Coder | System | 23 Jan 2021 18:16:54 |
| User entered 'HYPOXIA DUE TO RLL PNEUMONIA' | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:16:51 |

US3192734

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:38:11

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Yes (Y)' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:16:51 |

US3192734

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:38:11

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:16:51 |

US3192734

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:38:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:16:51 |

US3192734

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:38:11

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '18 Nov 2020' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:16:51 |

US3192734

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:38:11

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:16:51 |

US3192734

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:38:11

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 23 Jan 2021 18:16:51 |

US3192734

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:38:11

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:16:51 |

US3192734

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:38:11

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '25 Nov 2020' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:16:51 |

US3192734

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:38:11

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:16:51 |

US3192734

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:38:11

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 23 Jan 2021 18:16:51 |

US3192734

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:38:11

[Severity](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:16:51 |

US3192734

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:38:11

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Yes (Y)' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:16:51 |

US3192734

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:38:11

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:16:51 |

US3192734

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:38:11

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:16:51 |

US3192734

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:38:11

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '1' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:16:51 |

US3192734

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:38:11

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '18 Nov 2020' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:16:51 |

US3192734

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:38:11

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '25 Nov 2020' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:16:51 |

US3192734

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:38:11

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:16:51 |

US3192734

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:38:11

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:16:51 |

US3192734

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:38:11

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:16:51 |

US3192734

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:38:11

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:16:51 |

US3192734

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:38:11

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:16:51 |

US3192734

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:38:11

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Not Related (NOT RELATED)' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:16:51 |

US3192734

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:38:11

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Not Related (NOT RELATED)' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:16:51 |

US3192734

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:38:11

Action taken with investigational product

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User closed query 'PV Query: For the events hypoxia due to RLL pneumonia, valley fever, and difficulty breathing please update the action taken with study drug from none to not applicable since the last dose of study drug was given on 02 Nov 2020.' (Site from Safety). | (b) (4), (b) (6) | 08 Apr 2021 13:05:24 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| Query 'PV Query: For the events hypoxia due to RLL pneumonia, valley fever, and difficulty breathing please update the action taken with study drug from none to not applicable since the last dose of study drug was given on 02 Nov 2020.' answered with 'updated ' (Site from Safety). | Yvonne De Los Reyes (b) (4) | 08 Apr 2021 02:50:50 |
| User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error | Yvonne De Los Reyes (b) (4) | 08 Apr 2021 02:50:40 |
| User opened query 'PV Query: For the events hypoxia due to RLL pneumonia, valley fever, and difficulty breathing please update the action taken with study drug from none to not applicable since the last dose of study drug was given on 02 Nov 2020.' (Site from Safety). | (b) (4), (b) (6) | 24 Mar 2021 13:45:35 |
| User entered 'None (NONE)' | Crystal Mata (b) (4) | 23 Jan 2021 18:16:51 |

US3192734

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:38:11

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:16:51 |

US3192734

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:38:11

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '1' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:16:51 |

US3192734

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:38:11

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:16:51 |

US3192734

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:38:11

[Outcome](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:16:51 |

US3192734

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:38:11

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:16:51 |

US3192734

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:38:11

[Narrative](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'PER PI NOTE, ON 11/18/2020, HUSBAND REPORTED PATIENT LOOKED DAZED, CALLED 911 AND WAS ADMITTED. PATIENT RECEIVED IV ABX (VANCOMYCIN, METRONIDAZOLE, CEPHALOPSORIN) AND OXYGEN. PATIENT WAS DISCHARGED FROM HOSPITAL ON 11/25/2020 WITH OXYGEN AND DIAGNOSED WITH VALLEY FEVER AND SCAR TISSUE FROM PREVIOUS RADIATION. PATIENT HAS CHRONIC PULMONARY FIBROSIS DUE TO RADIATION TREATMENT FOR HISTORY OF HODGKIN'S LYMPHOMA IN 1999. PER PI, THIS SAE IS NOT RELATED TO INVESTIGATIONAL VACCINE.' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:16:51 |

US3192734

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:38:11

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 23 Jan 2021 18:16:51 |

US3192734

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:38:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 23 Jan 2021 18:16:51 |

US3192734

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:38:11

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 23 Jan 2021 18:16:51 |

US3192734

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:38:11

[AEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| Reviewed for Safety. | (b) (4) (D) (4), (b) (6) | 17 Mar 2021 14:57:45 |
| User entered 'USA-US097-2021-mRNA-1273-P301000006' | | 25 Jan 2021 17:49:03 |

US3192734

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:38:11

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User coded data point as SOC: Infections and infestations, HLGT: Fungal infectious disorders, HLT: Coccidioides infections, PT: Coccidioidomycosis, LLT: Valley fever - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) | 23 Jan 2021 18:22:01 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 23 Jan 2021 18:22:01 |
| Data point term sent to Coder | System | 23 Jan 2021 18:20:54 |
| User entered 'VALLEY FEVER' | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:19:56 |

US3192734

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:38:11

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Yes (Y)' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:19:56 |

US3192734

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:38:11

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:19:56 |

US3192734

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:38:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:19:56 |

US3192734

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:38:11

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '21 Nov 2020' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:19:56 |

US3192734

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:38:11

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:19:56 |

US3192734

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:38:11

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 23 Jan 2021 18:19:56 |

US3192734

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:38:11

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered 'No (N)' | Crystal Mata (b) (4) | 23 Jan 2021 18:19:56 |
| | (b) (4) | |

US3192734

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:38:11

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered '02 Dec 2020' | Crystal Mata (b) (4) | 23 Jan 2021 18:19:56 |
| | (b) (4) | |

US3192734

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:38:11

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:19:56 |

US3192734

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:38:11

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 23 Jan 2021 18:19:56 |

US3192734

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:38:11

[Severity](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:19:56 |

US3192734

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:38:11

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Yes (Y)' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:19:56 |

US3192734

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:38:11

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered '0' | Crystal Mata (b) (4) | 23 Jan 2021 18:19:56 |
| | (b) (4) | |

US3192734

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:38:11

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:19:56 |

US3192734

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:38:11

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'I' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:19:56 |

US3192734

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:38:11

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '18 Nov 2020' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:19:56 |

US3192734

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:38:11

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '25 Nov 2020' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:19:56 |

US3192734

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:38:11

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered 'No (N)' | Crystal Mata (b) (4) | 23 Jan 2021 18:19:56 |
| | (b) (4) | |

US3192734

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:38:11

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:19:56 |

US3192734

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:38:11

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:19:56 |

US3192734

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:38:11

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:19:56 |

US3192734

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:38:11

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:19:56 |

US3192734

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:38:11

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Not Related (NOT RELATED)' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:19:56 |

US3192734

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:38:11

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Not Related (NOT RELATED)' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:19:56 |

US3192734

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:38:11

Action taken with investigational product

| Audit | User | Time (GMT) |
|---|--|----------------------|
| User opened query 'PV Query: As the last dose of study drug was given on 02 Nov 2020, please consider updating the action taken with study drug from none to not applicable.' (Site from Safety). | (b) (4), (b) (6) | 03 May 2021 22:41:14 |
| User closed query 'PV Query: For the events hypoxia due to RLL pneumonia, valley fever, and difficulty breathing please update the action taken with study drug from none to not applicable since the last dose of study drug was given on 02 Nov 2020.' (Site from Safety). | | 12 Apr 2021 23:58:09 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| Query 'PV Query: For the events hypoxia due to RLL pneumonia, valley fever, and difficulty breathing please update the action taken with study drug from none to not applicable since the last dose of study drug was given on 02 Nov 2020.' answered with 'updated ' (Site from Safety). | (b) (4) Yvonne De Los Reyes (b) (4) | 08 Apr 2021 02:51:16 |
| User opened query 'PV Query: For the events hypoxia due to RLL pneumonia, valley fever, and difficulty breathing please update the action taken with study drug from none to not applicable since the last dose of study drug was given on 02 Nov 2020.' (Site from Safety). | (b) (4), (b) (6) | 24 Mar 2021 13:45:13 |
| User entered 'None (NONE)' | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:19:56 |

US3192734

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:38:11

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered '0' | Crystal Mata (b) (4) | 23 Jan 2021 18:19:56 |
| | (b) (4) | |

US3192734

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:38:11

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '1' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:19:56 |

US3192734

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:38:11

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered '0' | Crystal Mata (b) (4) | 23 Jan 2021 18:19:56 |
| | (b) (4) | |

US3192734

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:38:11

[Outcome](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:19:56 |

US3192734

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:38:11

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:19:56 |

US3192734

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:38:11

[Narrative](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'PER PI NOTE, ON 11/18/2020, HUSBAND REPORTED PATIENT LOOKED DAZED, CALLED 911 AND WAS ADMITTED. PATIENT RECEIVED IV ABX (VANCOMYCIN, METRONIDAZOLE, CEPHALOPSORIN) AND OXYGEN. PATIENT WAS DISCHARGED FROM HOSPITAL ON 11/25/2020 WITH OXYGEN AND DIAGNOSED WITH VALLEY FEVER AND SCAR TISSUE FROM PREVIOUS RADIATION. PATIENT HAS CHRONIC PULMONARY FIBROSIS DUE TO RADIATION TREATMENT FOR HISTORY OF HODGKIN'S LYMPHOMA IN 1999. PER PI, THIS SAE IS NOT RELATED TO INVESTIGATIONAL VACCINE.' | (b) (4) Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:19:56 |

US3192734

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:38:11

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 23 Jan 2021 18:19:56 |

US3192734

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:38:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 23 Jan 2021 18:19:56 |

US3192734

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:38:11

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 23 Jan 2021 18:19:56 |

US3192734

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:38:11

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:06 |
| | | |

US3192734

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:38:11

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:06 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Feelings and sensations NEC, PT: Chills, LLT: Chills - version MedDRA\\23.0. | Coder Import (b) (4) | 23 Jan 2021 18:25:01 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 23 Jan 2021 18:25:01 |
| Data point term sent to Coder | System | 23 Jan 2021 18:24:03 |
| User entered 'CHILLS' | Crystal Mata (b) (4) | 23 Jan 2021 18:23:10 |
| | (b) (4) | |

US3192734

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:38:11

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:06 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Yes (Y)' | Crystal Mata (b) (4) | 23 Jan 2021 18:23:10 |

US3192734

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:38:11

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:06 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Crystal Mata (b) (4) | 23 Jan 2021 18:23:10 |

US3192734

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:38:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:06 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Crystal Mata (b) (4) | 23 Jan 2021 18:23:10 |

US3192734

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:38:11

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:06 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '11 Nov 2020' | Crystal Mata (b) (4) | 23 Jan 2021 18:23:10 |

US3192734

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:38:11

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:06 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 18:23:10 |

US3192734

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:38:11

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:06 |
| User entered empty. | System | 23 Jan 2021 18:23:10 |

US3192734

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:38:11

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:06 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Crystal Mata (b) (4) | 23 Jan 2021 18:23:10 |

US3192734

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:38:11

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:06 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '11 Nov 2020' | Crystal Mata (b) (4) | 23 Jan 2021 18:23:10 |

US3192734

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:38:11

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:06 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 18:23:10 |

US3192734

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:38:11

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:06 |
| User entered empty. | System | 23 Jan 2021 18:23:10 |

US3192734

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:38:11

[Severity](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:06 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | (b) (4) Crystal Mata (b) (4) | 23 Jan 2021 18:23:10 |

US3192734

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:38:11

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:06 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Crystal Mata (b) (4) | 23 Jan 2021 18:23:10 |

US3192734

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:38:11

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:06 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Crystal Mata (b) (4) | 23 Jan 2021 18:23:10 |

US3192734

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:38:11

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:06 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Crystal Mata (b) (4) | 23 Jan 2021 18:23:10 |

US3192734

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:38:11

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:06 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Crystal Mata (b) (4) | 23 Jan 2021 18:23:10 |

US3192734

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:38:11

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:06 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 18:23:10 |

US3192734

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:38:11

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:06 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 18:23:10 |

US3192734

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:38:11

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:06 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 18:23:10 |

US3192734

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:38:11

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:06 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 18:23:10 |

US3192734

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:38:11

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:06 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Crystal Mata (b) (4) | 23 Jan 2021 18:23:10 |

US3192734

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:38:11

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:06 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Crystal Mata (b) (4) | 23 Jan 2021 18:23:10 |

US3192734

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:38:11

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:06 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Crystal Mata (b) (4) | 23 Jan 2021 18:23:10 |

US3192734

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:38:11

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:06 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Not Related (NOT RELATED)' | Crystal Mata (b) (4) | 23 Jan 2021 18:23:10 |

US3192734

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:38:11

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:06 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Not Related (NOT RELATED)' | Crystal Mata (b) (4) | 23 Jan 2021 18:23:10 |

US3192734

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:38:11

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:06 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'None (NONE)' | Crystal Mata (b) (4) | 23 Jan 2021 18:23:10 |

US3192734

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:38:11

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:06 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'I' | Crystal Mata (b) (4) | 23 Jan 2021 18:23:10 |

US3192734

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:38:11

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:06 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Crystal Mata (b) (4) | 23 Jan 2021 18:23:10 |

US3192734

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:38:11

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:06 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Crystal Mata (b) (4) | 23 Jan 2021 18:23:10 |

US3192734

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:38:11

[Outcome](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:06 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Crystal Mata (b) (4) | 23 Jan 2021 18:23:10 |

US3192734

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:38:11

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:06 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 18:23:10 |

US3192734

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:38:11

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:06 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 18:23:10 |

US3192734

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:38:11

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:06 |
| User entered '0' | System | 23 Jan 2021 18:23:10 |

US3192734

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:38:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:06 |
| User entered '1' | System | 23 Jan 2021 18:23:10 |

US3192734

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:38:11

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:06 |
| | | |

US3192734

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:38:11

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:12 |
| | | |

US3192734

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:38:11

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:12 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0. | Coder Import (b) (4) | 23 Jan 2021 18:38:02 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 23 Jan 2021 18:38:02 |
| Data point term sent to Coder | System | 23 Jan 2021 18:37:17 |
| User entered 'FATIGUE' | Crystal Mata (b) (4) | 23 Jan 2021 18:36:27 |

US3192734

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:38:11

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:12 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Yes (Y)' | Crystal Mata (b) (4) | 23 Jan 2021 18:36:27 |

US3192734

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:38:11

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:12 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User closed query 'Per DM CLR: Note, this is a solicited adverse reaction per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to "YES". Otherwise, clarify.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 09 Mar 2021 11:57:15 |
| Query 'Per DM CLR: Note, this is a solicited adverse reaction per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to "YES". Otherwise, clarify.' answered with 'updated ' (Site from DM). | Yvonne De Los Reyes (b) (4) | 07 Mar 2021 03:43:11 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Yvonne De Los Reyes (b) (4) | 07 Mar 2021 03:43:01 |
| User opened query 'Per DM CLR: Note, this is a solicited adverse reaction per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to "YES". Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6) | 20 Feb 2021 22:22:30 |
| User entered 'No (N)' | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:36:27 |

US3192734

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:38:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:12 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Crystal Mata (b) (4) | 23 Jan 2021 18:36:27 |

US3192734

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:38:11

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:12 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom FATIGUE on 03NOV2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 17 Mar 2021 06:22:13 |
| Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom FATIGUE on 03NOV2020. Please review if this should be reconciled. Else, provide clarification on dates.' answered with 'updated ' (Site from DM). | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:33:11 |
| User entered '03 Nov 2020' reason for change: Data Entry Error | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:33:06 |
| User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom FATIGUE on 03NOV2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM). | (b) (4), (b) (6) | 20 Feb 2021 22:22:38 |
| User entered '11 Nov 2020' | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:36:27 |

US3192734

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:38:11

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:12 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | |
| Query 'Data is required. Please provide.' answered with 'not collected ' (Site from System). | (b) (4), (b) (6) | 17 Mar 2021 06:22:10 |
| User opened query 'Data is required. Please provide.' (Site from System). | Yvonne De Los Reyes | 16 Mar 2021 17:33:14 |
| User entered empty. | (b) (4) | |
| | System | 16 Mar 2021 17:33:06 |
| | Crystal Mata (b) (4) | 23 Jan 2021 18:36:27 |
| | (b) (4) | |

US3192734

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:38:11

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:12 |
| User entered empty. | System | 23 Jan 2021 18:36:27 |

US3192734

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:38:11

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:12 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Crystal Mata (b) (4) | 23 Jan 2021 18:36:27 |

US3192734

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:38:11

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:12 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '02 Dec 2020' | Crystal Mata (b) (4) | 23 Jan 2021 18:36:27 |

US3192734

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:38:11

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:12 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 17 Mar 2021 06:22:21 |
| Query 'Data is required. Please provide.' answered with 'not collected ' (Site from System). | (b) (4), (b) (6) | 16 Mar 2021 17:33:18 |
| User opened query 'Data is required. Please provide.' (Site from System). | Yvonne De Los Reyes | 16 Mar 2021 17:33:06 |
| User entered empty. | System | 16 Mar 2021 17:33:06 |
| | Crystal Mata (b) (4) | 23 Jan 2021 18:36:27 |
| | (b) (4) | |

US3192734

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:38:11

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:12 |
| User entered empty. | System | 23 Jan 2021 18:36:27 |

US3192734

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:38:11

[Severity](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:12 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | (b) (4) Crystal Mata (b) (4) | 23 Jan 2021 18:36:27 |

US3192734

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:38:11

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:12 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Crystal Mata (b) (4) | 23 Jan 2021 18:36:27 |

US3192734

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:38:11

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:12 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Crystal Mata (b) (4) | 23 Jan 2021 18:36:27 |

US3192734

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:38:11

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:12 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Crystal Mata (b) (4) | 23 Jan 2021 18:36:27 |

US3192734

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:38:11

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:12 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Crystal Mata (b) (4) | 23 Jan 2021 18:36:27 |

US3192734

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:38:11

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:12 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 18:36:27 |

US3192734

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:38:11

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:12 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 18:36:27 |

US3192734

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:38:11

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:12 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 18:36:27 |

US3192734

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:38:11

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:12 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 18:36:27 |

US3192734

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:38:11

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:12 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Crystal Mata (b) (4) | 23 Jan 2021 18:36:27 |

US3192734

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:38:11

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:12 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Crystal Mata (b) (4) | 23 Jan 2021 18:36:27 |

US3192734

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:38:11

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:12 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Crystal Mata (b) (4) | 23 Jan 2021 18:36:27 |

US3192734

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:38:11

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:12 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Related (RELATED)' reason for change: Data Entry Error | (b) (4) Yvonne De Los Reyes | 07 Mar 2021 03:43:01 |
| User entered 'Not Related (NOT RELATED)' | (b) (4) Crystal Mata (b) (4) | 23 Jan 2021 18:36:27 |

US3192734

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:38:11

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:12 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Not Related (NOT RELATED)' | Crystal Mata (b) (4) | 23 Jan 2021 18:36:27 |

US3192734

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:38:11

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:12 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'None (NONE)' | Crystal Mata (b) (4) | 23 Jan 2021 18:36:27 |

US3192734

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:38:11

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:12 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'I' | Crystal Mata (b) (4) | 23 Jan 2021 18:36:27 |

US3192734

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:38:11

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:12 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Crystal Mata (b) (4) | 23 Jan 2021 18:36:27 |

US3192734

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:38:11

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:12 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Crystal Mata (b) (4) | 23 Jan 2021 18:36:27 |

US3192734

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:38:11

[Outcome](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:12 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Crystal Mata (b) (4) | 23 Jan 2021 18:36:27 |

US3192734

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:38:11

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:12 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 18:36:27 |

US3192734

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:38:11

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:12 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 18:36:27 |

US3192734

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:38:11

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:12 |
| User entered '0' | System | 23 Jan 2021 18:36:27 |

US3192734

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:38:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:12 |
| User entered '1' | System | 23 Jan 2021 18:36:27 |

US3192734

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:38:11

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:12 |
| | | |

US3192734

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:38:11

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:17 |
| | | |

US3192734

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:38:11

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:17 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: General body pain - version MedDRA\\23.0. | Coder Import (b) (4) | 23 Jan 2021 18:39:01 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 23 Jan 2021 18:39:01 |
| Data point term sent to Coder | System | 23 Jan 2021 18:38:17 |
| User entered 'BODY ACHES' | Crystal Mata (b) (4) | 23 Jan 2021 18:38:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:38:11

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:17 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Yes (Y)' | Crystal Mata (b) (4) | 23 Jan 2021 18:38:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:38:11

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:17 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User closed query 'Per DM CLR: Please verify if this pertains to MUSCLE ACHES in eDiary. If yes, note tht this is a solicited adverse reaction per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to "YES". Otherwise, clarify.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 09 Mar 2021 11:57:24 |
| Query 'Per DM CLR: Please verify if this pertains to MUSCLE ACHES in eDiary. If yes, note tht this is a solicited adverse reaction per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to "YES". Otherwise, clarify.' answered with 'updated' (Site from DM). | Yvonne De Los Reyes (b) (4) | 07 Mar 2021 03:43:40 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Yvonne De Los Reyes (b) (4) | 07 Mar 2021 03:43:30 |
| User opened query 'Per DM CLR: Please verify if this pertains to MUSCLE ACHES in eDiary. If yes, note tht this is a solicited adverse reaction per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to "YES". Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6) | 20 Feb 2021 22:22:53 |
| User entered 'No (N)' | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:38:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:38:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:17 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Crystal Mata (b) (4) | 23 Jan 2021 18:38:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:38:11

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:17 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User closed query 'Per DM CLR: Please verify if this pertains to MUSCLE ACHES in eDiary. If yes, note that this AE start date does not match the Diary initial start date of Solicited Symptom MYALGIA on 05NOV2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 17 Mar 2021 06:22:35 |
| Query 'Per DM CLR: Please verify if this pertains to MUSCLE ACHES in eDiary. If yes, note that this AE start date does not match the Diary initial start date of Solicited Symptom MYALGIA on 05NOV2020. Please review if this should be reconciled. Else, provide clarification on dates.' answered with 'updated ' (Site from DM). | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:33:43 |
| User entered '05 Nov 2020' reason for change: Data Entry Error | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:33:38 |
| User opened query 'Per DM CLR: Please verify if this pertains to MUSCLE ACHES in eDiary. If yes, note that this AE start date does not match the Diary initial start date of Solicited Symptom MYALGIA on 05NOV2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM). | (b) (4), (b) (6) | 20 Feb 2021 22:23:04 |
| User entered '11 Nov 2020' | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:38:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:38:11

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:17 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 18:38:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:38:11

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:17 |
| User entered empty. | System | 23 Jan 2021 18:38:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:38:11

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:17 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Crystal Mata (b) (4) | 23 Jan 2021 18:38:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:38:11

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:17 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '18 Nov 2020' | Crystal Mata (b) (4) | 23 Jan 2021 18:38:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:38:11

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:17 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 18:38:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:38:11

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:17 |
| User entered empty. | System | 23 Jan 2021 18:38:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:38:11

[Severity](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:17 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | (b) (4) Crystal Mata (b) (4) | 23 Jan 2021 18:38:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:38:11

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:17 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Crystal Mata (b) (4) | 23 Jan 2021 18:38:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:38:11

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:17 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Crystal Mata (b) (4) | 23 Jan 2021 18:38:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:38:11

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:17 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Crystal Mata (b) (4) | 23 Jan 2021 18:38:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:38:11

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:17 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Crystal Mata (b) (4) | 23 Jan 2021 18:38:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:38:11

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:17 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 18:38:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:38:11

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:17 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 18:38:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:38:11

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:17 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 18:38:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:38:11

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:17 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 18:38:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:38:11

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:17 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Crystal Mata (b) (4) | 23 Jan 2021 18:38:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:38:11

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:17 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Crystal Mata (b) (4) | 23 Jan 2021 18:38:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:38:11

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:17 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Crystal Mata (b) (4) | 23 Jan 2021 18:38:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:38:11

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:17 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Related (RELATED)' reason for change: Data Entry Error | (b) (4) Yvonne De Los Reyes | 07 Mar 2021 03:43:30 |
| User entered 'Not Related (NOT RELATED)' | (b) (4) Crystal Mata (b) (4) | 23 Jan 2021 18:38:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:38:11

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:17 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Not Related (NOT RELATED)' | Crystal Mata (b) (4) | 23 Jan 2021 18:38:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:38:11

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:17 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'None (NONE)' | Crystal Mata (b) (4) | 23 Jan 2021 18:38:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:38:11

[None](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:17 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' reason for change: Data Entry Error | (b) (4) | |
| | Crystal Mata (b) (4) | 23 Jan 2021 18:40:52 |
| User entered '1' | (b) (4) | |
| | Crystal Mata (b) (4) | 23 Jan 2021 18:38:11 |
| | (b) (4) | |

US3192734

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:38:11

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:17 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '1' reason for change: Data Entry Error | (b) (4) | |
| | Crystal Mata (b) (4) | 23 Jan 2021 18:40:52 |
| User entered '0' | (b) (4) | |
| | Crystal Mata (b) (4) | 23 Jan 2021 18:38:11 |
| | (b) (4) | |

US3192734

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:38:11

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:17 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Crystal Mata (b) (4) | 23 Jan 2021 18:38:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:38:11

[Outcome](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:17 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Crystal Mata (b) (4) | 23 Jan 2021 18:38:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:38:11

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:17 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 18:38:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:38:11

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:17 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 18:38:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:38:11

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:17 |
| User entered '0' | System | 23 Jan 2021 18:38:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:38:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:17 |
| User entered '1' | System | 23 Jan 2021 18:38:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:38:11

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:17 |
| | | |

US3192734

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:38:11

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:25 |
| | | |

US3192734

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:38:11

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) | 23 Jan 2021 18:41:17 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 23 Jan 2021 18:41:17 |
| Data point term sent to Coder | System | 23 Jan 2021 18:40:18 |
| User entered 'HEADACHE' | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:39:28 |

US3192734

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:38:11

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Yes (Y)' | Crystal Mata (b) (4) | 23 Jan 2021 18:39:28 |

US3192734

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:38:11

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User closed query 'Per DM CLR: Note, this is a solicited adverse reaction per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to "YES". Otherwise, clarify.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 17 Mar 2021 06:22:46 |
| Query 'Per DM CLR: Note, this is a solicited adverse reaction per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to "YES". Otherwise, clarify.' answered with 'updated ' (Site from DM). | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:34:15 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:34:01 |
| User opened query 'Per DM CLR: Note, this is a solicited adverse reaction per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to "YES". Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6) | 20 Feb 2021 22:23:22 |
| User entered 'No (N)' | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:39:28 |

US3192734

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:38:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Crystal Mata (b) (4) | 23 Jan 2021 18:39:28 |

US3192734

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:38:11

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom HEADACHE on 05NOV2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 17 Mar 2021 06:22:49 |
| Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom HEADACHE on 05NOV2020. Please review if this should be reconciled. Else, provide clarification on dates.' answered with 'updated ' (Site from DM). | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:34:19 |
| User entered '05 Nov 2020' reason for change: Data Entry Error | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:34:01 |
| User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom HEADACHE on 05NOV2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM). | (b) (4), (b) (6) | 20 Feb 2021 22:23:30 |
| User entered '11 Nov 2020' | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:39:28 |

US3192734

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:38:11

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 18:39:28 |

US3192734

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:38:11

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:25 |
| User entered empty. | System | 23 Jan 2021 18:39:28 |

US3192734

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:38:11

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Crystal Mata (b) (4) | 23 Jan 2021 18:39:28 |

US3192734

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:38:11

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '18 Nov 2020' | Crystal Mata (b) (4) | 23 Jan 2021 18:39:28 |

US3192734

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:38:11

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 18:39:28 |

US3192734

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:38:11

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:25 |
| User entered empty. | System | 23 Jan 2021 18:39:28 |

US3192734

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:38:11

[Severity](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | (b) (4) Crystal Mata (b) (4) | 23 Jan 2021 18:39:28 |

US3192734

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:38:11

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Crystal Mata (b) (4) | 23 Jan 2021 18:39:28 |

US3192734

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:38:11

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Crystal Mata (b) (4) | 23 Jan 2021 18:39:28 |

US3192734

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:38:11

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Crystal Mata (b) (4) | 23 Jan 2021 18:39:28 |

US3192734

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:38:11

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Crystal Mata (b) (4) | 23 Jan 2021 18:39:28 |

US3192734

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:38:11

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 18:39:28 |

US3192734

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:38:11

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 18:39:28 |

US3192734

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:38:11

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 18:39:28 |

US3192734

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:38:11

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 18:39:28 |

US3192734

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:38:11

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Crystal Mata (b) (4) | 23 Jan 2021 18:39:28 |

US3192734

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:38:11

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Crystal Mata (b) (4) | 23 Jan 2021 18:39:28 |

US3192734

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:38:11

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Crystal Mata (b) (4) | 23 Jan 2021 18:39:28 |

US3192734

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:38:11

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| 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 | 23 Jan 2021 18:40:09 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error | System | 23 Jan 2021 18:40:09 |
| User opened query 'Data is required. Please complete.' (Site from System). | Crystal Mata (b) (4) | 23 Jan 2021 18:40:09 |
| User entered empty. | (b) (4) | |
| | System | 23 Jan 2021 18:39:28 |
| | Crystal Mata (b) (4) | 23 Jan 2021 18:39:28 |
| | (b) (4) | |

US3192734

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:38:11

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| 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 | 23 Jan 2021 18:40:09 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error | System | 23 Jan 2021 18:40:09 |
| User opened query 'Data is required. Please complete.' (Site from System). | Crystal Mata (b) (4) | 23 Jan 2021 18:40:09 |
| User entered empty. | (b) (4) | |
| | System | 23 Jan 2021 18:39:28 |
| | Crystal Mata (b) (4) | 23 Jan 2021 18:39:28 |
| | (b) (4) | |

US3192734

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:38:11

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| 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 | 23 Jan 2021 18:40:09 |
| User entered 'None (NONE)' reason for change: Data Entry Error | System | 23 Jan 2021 18:40:09 |
| User opened query 'Data is required. Please complete.' (Site from System). | Crystal Mata (b) (4) | 23 Jan 2021 18:40:09 |
| User entered empty. | (b) (4) | |
| | System | 23 Jan 2021 18:39:28 |
| | Crystal Mata (b) (4) | 23 Jan 2021 18:39:28 |
| | (b) (4) | |

US3192734

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:38:11

[None](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' reason for change: Data Entry Error | (b) (4) | |
| | Crystal Mata (b) (4) | 23 Jan 2021 18:40:19 |
| User entered '1' | (b) (4) | |
| | Crystal Mata (b) (4) | 23 Jan 2021 18:39:28 |
| | (b) (4) | |

US3192734

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:38:11

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '1' reason for change: Data Entry Error | (b) (4) | |
| | Crystal Mata (b) (4) | 23 Jan 2021 18:40:19 |
| User entered '0' | (b) (4) | |
| | Crystal Mata (b) (4) | 23 Jan 2021 18:39:28 |
| | (b) (4) | |

US3192734

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:38:11

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Crystal Mata (b) (4) | 23 Jan 2021 18:39:28 |

US3192734

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:38:11

[Outcome](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4) Crystal Mata (b) (4) | 23 Jan 2021 18:39:28 |

US3192734

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:38:11

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 18:39:28 |

US3192734

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:38:11

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 18:39:28 |

US3192734

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:38:11

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:25 |
| User entered '0' | System | 23 Jan 2021 18:39:28 |

US3192734

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:38:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:25 |
| User entered '1' | System | 23 Jan 2021 18:39:28 |

US3192734

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:38:11

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:25 |
| | | |

US3192734

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:38:11

[AEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 01 Feb 2021 19:48:44 |
| User entered 'USA-US097-2021-mRNA-1273-P301000006' | | 01 Feb 2021 19:45:09 |

US3192734

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:38:11

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of OBSTRUCTIVE AIRWAY LIMITATION/CHRONIC PULMONARY FIBROSIS. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6) | 13 Apr 2021 07:18:00 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Lower respiratory tract disorders (excl obstruction and infection), HLT: Parenchymal lung disorders NEC, PT: Pulmonary fibrosis, LLT: Pulmonary fibrosis - version MedDRA\23.0. | Coder Import (b) (4) | 08 Apr 2021 04:57:19 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) | 08 Apr 2021 04:57:19 |
| Data point term sent to Coder | System | 08 Apr 2021 02:55:42 |
| Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of OBSTRUCTIVE AIRWAY LIMITATION/CHRONIC PULMONARY FIBROSIS. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' answered with 'updated ' (Site from DM). | Yvonne De Los Reyes (b) (4) | 08 Apr 2021 02:55:01 |
| Coding entries removed. | Yvonne De Los Reyes (b) (4) | 08 Apr 2021 02:54:50 |
| User entered 'worsening of chronic pulmonary fibrosis' reason for change: Data Entry Error | Yvonne De Los Reyes (b) (4) | 08 Apr 2021 02:54:50 |
| User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of OBSTRUCTIVE AIRWAY LIMITATION/CHRONIC PULMONARY FIBROSIS. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6) | 31 Mar 2021 08:25:40 |

US3192734

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:38:11

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Difficulty breathing - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 31 Jan 2021 20:45:47 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 31 Jan 2021 20:45:47 |
| Data point term sent to Coder | System | 31 Jan 2021 20:44:52 |
| User entered 'difficulty breathing' | Saysamone Banks (b) (4) (b) (4) | 31 Jan 2021 20:44:24 |

US3192734

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:38:11

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Yes (Y)' | Saysamone Banks (b) (4) | 31 Jan 2021 20:44:24 |

US3192734

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:38:11

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | (b) (4) Saysamone Banks (b) (4) | 31 Jan 2021 20:44:24 |
| | (b) (4) | |

US3192734

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:38:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | (b) (4) Saysamone Banks (b) (4) | 31 Jan 2021 20:44:24 |
| | (b) (4) | |

US3192734

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:38:11

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '11 Nov 2020' | (b) (4) Saysamone Banks (b) (4) | 31 Jan 2021 20:44:24 |
| | (b) (4) | |

US3192734

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:38:11

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | (b) (4) Saysamone Banks (b) (4) | 31 Jan 2021 20:44:24 |
| | (b) (4) | |

US3192734

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:38:11

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Jan 2021 20:44:24 |

US3192734

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:38:11

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered 'No (N)' | Saysamone Banks (b) (4) | 31 Jan 2021 20:44:24 |
| | (b) (4) | |

US3192734

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:38:11

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '22 Nov 2020' | (b) (4) Saysamone Banks (b) (4) | 31 Jan 2021 20:44:24 |
| | (b) (4) | |

US3192734

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:38:11

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | (b) (4) Saysamone Banks (b) (4) | 31 Jan 2021 20:44:24 |
| | (b) (4) | |

US3192734

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:38:11

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Jan 2021 20:44:24 |

US3192734

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:38:11

[Severity](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | (b) (4) Saysamone Banks (b) (4) | 31 Jan 2021 20:44:24 |

US3192734

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:38:11

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System). | (b) (4) System | 31 Jan 2021 20:46:44 |
| User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System). | System | 31 Jan 2021 20:44:24 |
| User entered 'Yes (Y)' | Saysamone Banks (b) (4) (b) (4) | 31 Jan 2021 20:44:24 |

US3192734

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:38:11

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered '0' | Saysamone Banks (b) (4) | 31 Jan 2021 20:44:24 |
| | (b) (4) | |

US3192734

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:38:11

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered '0' | Saysamone Banks (b) (4) | 31 Jan 2021 20:44:24 |
| | (b) (4) | |

US3192734

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:38:11

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '1' reason for change: Data Entry Error | (b) (4) | |
| | Saysamone Banks (b) (4) | 31 Jan 2021 20:46:44 |
| | (b) (4) | |
| User entered '0' | Saysamone Banks (b) (4) | 31 Jan 2021 20:44:24 |
| | (b) (4) | |

US3192734

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:38:11

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '18 Nov 2020' reason for change: Data Entry Error | (b) (4) | |
| | Saysamone Banks (b) (4) | 31 Jan 2021 20:46:44 |
| User entered empty. | (b) (4) | |
| | Saysamone Banks (b) (4) | 31 Jan 2021 20:44:24 |
| | (b) (4) | |

US3192734

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:38:11

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '25 Nov 2020' reason for change: Data Entry Error | (b) (4) | |
| | Saysamone Banks (b) (4) | 31 Jan 2021 20:46:44 |
| User entered empty. | (b) (4) | |
| | Saysamone Banks (b) (4) | 31 Jan 2021 20:44:24 |
| | (b) (4) | |

US3192734

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:38:11

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4) Saysamone Banks (b) (4) | 31 Jan 2021 20:46:44 |
| User entered empty. | Saysamone Banks (b) (4) | 31 Jan 2021 20:44:24 |

US3192734

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:38:11

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | (b) (4) Saysamone Banks (b) (4) | 31 Jan 2021 20:44:24 |
| | (b) (4) | |

US3192734

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:38:11

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | (b) (4) Saysamone Banks (b) (4) | 31 Jan 2021 20:44:24 |
| | (b) (4) | |

US3192734

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:38:11

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | (b) (4) Saysamone Banks (b) (4) (b) (4) | 31 Jan 2021 20:44:24 |

US3192734

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:38:11

[Other medically important event](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '1' reason for change: Data Entry Error | (b) (4) | |
| | Saysamone Banks (b) (4) | 31 Jan 2021 20:46:44 |
| | (b) (4) | |
| User entered '0' | Saysamone Banks (b) (4) | 31 Jan 2021 20:44:24 |
| | (b) (4) | |

US3192734

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:38:11

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Not Related (NOT RELATED)' | (b) (4) Saysamone Banks (b) (4) | 31 Jan 2021 20:44:24 |

US3192734

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:38:11

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Not Related (NOT RELATED)' | (b) (4) Saysamone Banks (b) (4) | 31 Jan 2021 20:44:24 |

US3192734

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:38:11

Action taken with investigational product

| Audit | User | Time (GMT) |
|--|--|--|
| User opened query 'PV Query: As the last dose of study drug was given on 02 Nov 2020, please consider updating the action taken with study drug from none to not applicable.' (Site from Safety). User signature succeeded. | (b) (4), (b) (6) (b) (4) | 03 May 2021 22:42:19 |
| User closed query 'Data is required. Please complete.' (Site from System). Query 'Data is required. Please complete.' answered by data change (Site from System). | John McGettigan (b) (4) (b) (4) System | 08 Apr 2021 12:37:15 31 Jan 2021 20:46:44 31 Jan 2021 20:46:44 |
| User entered 'None (NONE)' reason for change: Data Entry Error | Saysamone Banks (b) (4) (b) (4) | 31 Jan 2021 20:46:44 |
| User opened query 'Data is required. Please complete.' (Site from System). User entered empty. | System Saysamone Banks (b) (4) (b) (4) | 31 Jan 2021 20:44:24 31 Jan 2021 20:44:24 |

US3192734

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:38:11

None

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| 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) (6) | 13 Apr 2021 07:18:04 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| 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 'site had made multiple attempts to obtain records, will continue with efforts ' (Site from DM). | Yvonne De Los Reyes (b) (4) | 08 Apr 2021 02:54:35 |
| 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) | 31 Mar 2021 08:24:53 |
| User entered '1' reason for change: Data Entry Error | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:34:39 |
| User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). | System | 31 Jan 2021 20:46:44 |
| User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). | System | 31 Jan 2021 20:44:24 |
| User entered '0' | Saysamone Banks (b) (4) | 31 Jan 2021 20:44:24 |

US3192734

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:38:11

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|------------------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 17 Mar 2021 06:23:25 |
| Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'updated ' (Site from DM). | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:36:18 |
| User entered '0' reason for change: Data Entry Error | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:34:39 |
| User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM). | (b) (4), (b) (6) | 20 Feb 2021 22:23:43 |
| User entered '1' reason for change: Data Entry Error | Saysamone Banks (b) (4) | (b) (4) 31 Jan 2021 20:46:44 |
| User entered '0' | Saysamone Banks (b) (4) | (b) (4) 31 Jan 2021 20:44:24 |

US3192734

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:38:11

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | (b) (4) Saysamone Banks (b) (4) | 31 Jan 2021 20:44:24 |
| | (b) (4) | |

US3192734

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:38:11

[Outcome](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4) Saysamone Banks (b) (4) | 31 Jan 2021 20:44:24 |

US3192734

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:38:11

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | (b) (4) Saysamone Banks (b) (4) (b) (4) | 31 Jan 2021 20:44:24 |

US3192734

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:38:11

[Narrative](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User closed query 'Per DM CLR: Narrative = PREVIOUS RADIATION. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM). | (b) (4), (b) (6) | 13 Apr 2021 07:18:07 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| Query 'Per DM CLR: Narrative = PREVIOUS RADIATION. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' answered with 'updated ' (Site from DM). | Yvonne De Los Reyes (b) (4) | 08 Apr 2021 02:54:40 |
| User opened query 'Per DM CLR: Narrative = PREVIOUS RADIATION. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM). | (b) (4), (b) (6) | 31 Mar 2021 08:25:32 |
| User entered 'PER PI NOTE, ON 11/18/2020, HUSBAND REPORTED PATIENT LOOKED DAZED, CALLED 911 AND WAS ADMITTED. PATIENT RECEIVED IV ABX (VANCOMYCIN, METRONIDAZOLE, CEPHALOSPORIN) AND OXYGEN. PATIENT WAS DISCHARGED FROM HOSPITAL ON 11/25/2020 WITH OXYGEN AND DIAGNOSED WITH VALLEY FEVER AND SCAR TISSUE FROM PREVIOUS RADIATION. PATIENT HAS CHRONIC PULMONARY FIBROSIS DUE TO RADIATION TREATMENT FOR HISTORY OF HODGKIN'S LYMPHOMA IN 1999. PER PI, THIS SAE IS NOT RELATED TO INVESTIGATIONAL VACCINE.' | Saysamone Banks (b) (4) | 31 Jan 2021 20:44:24 |

US3192734

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:38:11

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 31 Jan 2021 20:44:24 |

US3192734

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:38:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 31 Jan 2021 20:44:24 |

US3192734

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:38:11

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 31 Jan 2021 20:46:44 |

US3192734

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:38:11

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:28 |
| | | |

US3192734

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:38:11

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:28 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site pain, LLT: Pain injection site - version MedDRA\\23.0. | Coder Import (b) (4) | 16 Mar 2021 18:52:53 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 16 Mar 2021 18:52:53 |
| Data point term sent to Coder | System | 16 Mar 2021 18:52:09 |
| User entered 'sore arm post injection' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:51:31 |

US3192734

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:38:11

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:28 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:51:31 |

US3192734

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:38:11

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:28 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:51:31 |

US3192734

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:38:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:28 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:51:31 |

US3192734

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:38:11

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:28 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '30 Jan 2021' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:51:31 |

US3192734

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:38:11

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:28 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | |
| Query 'Data is required. Please provide.' answered with 'not collected ' (Site from System). | (b) (4), (b) (6) | 17 Mar 2021 06:29:56 |
| User opened query 'Data is required. Please provide.' (Site from System). | Yvonne De Los Reyes | 16 Mar 2021 18:51:35 |
| User entered empty. | (b) (4) | |
| | System | 16 Mar 2021 18:51:31 |
| | Yvonne De Los Reyes | 16 Mar 2021 18:51:31 |
| | (b) (4) | |

US3192734

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:38:11

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:28 |
| User entered empty. | System | 16 Mar 2021 18:51:31 |

US3192734

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:38:11

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:28 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:51:31 |

US3192734

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:38:11

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:28 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '31 Jan 2021' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:51:31 |

US3192734

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:38:11

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:28 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | |
| Query 'Data is required. Please provide.' answered with 'not collected ' (Site from System). | (b) (4), (b) (6) | 17 Mar 2021 06:29:59 |
| User opened query 'Data is required. Please provide.' (Site from System). | Yvonne De Los Reyes | 16 Mar 2021 18:51:39 |
| User entered empty. | (b) (4) | |
| | System | 16 Mar 2021 18:51:31 |
| | Yvonne De Los Reyes | 16 Mar 2021 18:51:31 |
| | (b) (4) | |

US3192734

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:38:11

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:28 |
| User entered empty. | System | 16 Mar 2021 18:51:31 |

US3192734

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:38:11

[Severity](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:28 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:51:31 |

US3192734

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:38:11

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:28 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:51:31 |

US3192734

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:38:11

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:28 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:51:31 |

US3192734

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:38:11

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:28 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:51:31 |

US3192734

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:38:11

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:28 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:51:31 |

US3192734

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:38:11

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:28 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:51:31 |

US3192734

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:38:11

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:28 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:51:31 |

US3192734

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:38:11

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:28 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:51:31 |

US3192734

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:38:11

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:28 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:51:31 |

US3192734

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:38:11

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:28 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:51:31 |

US3192734

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:38:11

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:28 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:51:31 |

US3192734

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:38:11

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:28 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:51:31 |

US3192734

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:38:11

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:28 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Related (RELATED)' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:51:31 |

US3192734

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:38:11

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:28 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Not Related (NOT RELATED)' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:51:31 |

US3192734

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:38:11

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:28 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Not Applicable (NOT APPLICABLE)' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:51:31 |

US3192734

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:38:11

[None](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:28 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '1' reason for change: Data Entry Error | (b) (4) | 08 Apr 2021 02:56:59 |
| User entered '0' | Yvonne De Los Reyes | 16 Mar 2021 18:51:31 |
| | (b) (4) | |

US3192734

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:38:11

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:28 |
| User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM). | | 13 Apr 2021 07:17:30 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'updated' (Site from DM). | (b) (4) Yvonne De Los Reyes | 08 Apr 2021 02:57:05 |
| User entered '0' reason for change: Data Entry Error | (b) (4) Yvonne De Los Reyes | 08 Apr 2021 02:56:59 |
| User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM). | (b) (4), (b) (6) | 31 Mar 2021 08:23:31 |
| User entered '1' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:51:31 |

US3192734

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:38:11

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:28 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:51:31 |

US3192734

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:38:11

[Outcome](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:28 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:51:31 |

US3192734

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:38:11

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:28 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:51:31 |

US3192734

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:38:11

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:28 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:51:31 |

US3192734

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:38:11

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:28 |
| User entered '0' | System | 16 Mar 2021 18:51:31 |

US3192734

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:38:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:28 |
| User entered '0' | System | 16 Mar 2021 18:51:31 |

US3192734

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:38:11

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:28 |
| | | |

US3192734

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:38:11

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:31 |
| | | |

US3192734

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:38:11

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:31 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0. | Coder Import (b) (4) | 16 Mar 2021 18:53:53 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 16 Mar 2021 18:53:53 |
| Data point term sent to Coder | System | 16 Mar 2021 18:53:13 |
| User entered 'fatigue' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:52:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:38:11

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:31 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:52:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:38:11

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:31 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:52:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:38:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:31 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:52:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:38:11

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:31 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '02 Mar 2021' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:52:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:38:11

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:31 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4), (b) (6) | 17 Mar 2021 06:30:15 |
| Query 'Data is required. Please provide.' answered with 'not collected ' (Site from System). | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:52:15 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 16 Mar 2021 18:52:11 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:52:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:38:11

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:31 |
| User entered empty. | System | 16 Mar 2021 18:52:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:38:11

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:31 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:52:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:38:11

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:31 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '03 Mar 2021' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:52:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:38:11

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:31 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4), (b) (6) | 17 Mar 2021 06:30:17 |
| Query 'Data is required. Please provide.' answered with 'not collected ' (Site from System). | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:52:18 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 16 Mar 2021 18:52:11 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:52:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:38:11

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:31 |
| User entered empty. | System | 16 Mar 2021 18:52:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:38:11

[Severity](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:31 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:52:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:38:11

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:31 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:52:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:38:11

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:31 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:52:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:38:11

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:31 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:52:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:38:11

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:31 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:52:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:38:11

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:31 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:52:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:38:11

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:31 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:52:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:38:11

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:31 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:52:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:38:11

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:31 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:52:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:38:11

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:31 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:52:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:38:11

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:31 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:52:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:38:11

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:31 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:52:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:38:11

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:31 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Related (RELATED)' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:52:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:38:11

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:31 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Not Related (NOT RELATED)' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:52:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:38:11

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:31 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4) Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:52:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:38:11

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:31 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'I' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:52:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:38:11

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:31 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:52:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:38:11

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:31 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:52:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:38:11

[Outcome](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:31 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:52:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:38:11

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:31 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:52:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:38:11

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:31 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:52:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:38:11

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:31 |
| User entered '0' | System | 16 Mar 2021 18:52:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:38:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:31 |
| User entered '0' | System | 16 Mar 2021 18:52:11 |

US3192734

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:38:11

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:31 |
| | | |

US3192734

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:38:11

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:38 |
| | | |

US3192734

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:38:11

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:38 |
| User closed query 'Per DM CLR: Please review and update AE term to reflect the specific body location and type of JOINT ACHES. Please reconcile with the ConMed eCRF so there is an appropriate match. ' (Site from DM). | | 13 Apr 2021 07:17:49 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Generalized joint pain - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) (b) (4) | 08 Apr 2021 03:41:25 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 08 Apr 2021 03:41:25 |
| Query 'Per DM CLR: Please review and update AE term to reflect the specific body location and type of JOINT ACHES. Please reconcile with the ConMed eCRF so there is an appropriate match. ' answered with 'updated ' (Site from DM). | Yvonne De Los Reyes (b) (4) | 08 Apr 2021 02:57:54 |
| Data point term sent to Coder | System | 08 Apr 2021 02:57:43 |
| Coding entries removed. | Yvonne De Los Reyes (b) (4) | 08 Apr 2021 02:57:34 |
| User entered 'generalized joint aches' reason for change: Data Entry Error | Yvonne De Los Reyes (b) (4) | 08 Apr 2021 02:57:34 |
| User opened query 'Per DM CLR: Please review and update AE term to reflect the specific body location and type of JOINT ACHES. Please reconcile with the ConMed eCRF so there is an appropriate match. ' (Site from DM). | (b) (4), (b) (6) | 31 Mar 2021 08:23:46 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Joint ache - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 16 Mar 2021 18:53:54 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 16 Mar 2021 18:53:54 |
| Data point term sent to Coder | System | 16 Mar 2021 18:53:11 |
| User entered 'joint aches' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:53:09 |

US3192734

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:38:11

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:53:09 |

US3192734

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:38:11

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Yes (Y)' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:53:09 |

US3192734

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:38:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:53:09 |

US3192734

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:38:11

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '05 Nov 2020' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:53:09 |

US3192734

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:38:11

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:53:09 |

US3192734

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:38:11

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:38 |
| User entered empty. | System | 16 Mar 2021 18:53:09 |

US3192734

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:38:11

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:53:09 |

US3192734

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:38:11

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '16 Nov 2020' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:53:09 |

US3192734

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:38:11

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:53:09 |

US3192734

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:38:11

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:38 |
| User entered empty. | System | 16 Mar 2021 18:53:09 |

US3192734

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:38:11

[Severity](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:53:09 |

US3192734

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:38:11

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:53:09 |

US3192734

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:38:11

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:53:09 |

US3192734

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:38:11

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:53:09 |

US3192734

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:38:11

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:53:09 |

US3192734

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:38:11

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:53:09 |

US3192734

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:38:11

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:53:09 |

US3192734

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:38:11

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:53:09 |

US3192734

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:38:11

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:53:09 |

US3192734

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:38:11

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:53:09 |

US3192734

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:38:11

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:53:09 |

US3192734

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:38:11

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:53:09 |

US3192734

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:38:11

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Related (RELATED)' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:53:09 |

US3192734

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:38:11

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Not Related (NOT RELATED)' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:53:09 |

US3192734

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:38:11

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Not Applicable (NOT APPLICABLE)' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:53:09 |

US3192734

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:38:11

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'I' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:53:09 |

US3192734

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:38:11

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:53:09 |

US3192734

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:38:11

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:53:09 |

US3192734

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:38:11

[Outcome](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:53:09 |

US3192734

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:38:11

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:53:09 |

US3192734

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:38:11

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 18:53:09 |

US3192734

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:38:11

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:38 |
| User entered '0' | System | 16 Mar 2021 18:53:09 |

US3192734

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:38:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:38 |
| User entered '0' | System | 16 Mar 2021 18:53:09 |

US3192734

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:38:11

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:03:38 |
| | | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:38:11

Were any prior/concomitant medications and/or vaccinations taken?

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 16:54:10 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User closed query 'Per DM CLR: Per Diary Dose 2 Day 4-7, Headache (General) = 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, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 26 Jan 2021 05:12:07 |
| Query 'Per DM CLR: Per Diary Dose 2 Day 4-7, Headache (General) = 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, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'ALL MEDICATIONS HAVE BEEN ENTERED IN THE CON-MED ECRFS. THANK YOU.' (Site from DM). | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 20:06:28 |
| User opened query 'Per DM CLR: Per Diary Dose 2 Day 4-7, Headache (General) = 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, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM). | (b) (4), (b) (6) | 23 Jan 2021 14:56:58 |
| User entered 'Yes (Y)' | Saysamone Banks (b) (4) (b) (4) | 05 Oct 2020 16:33:31 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:38:11

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, NON-SELECTIVE, PRODUCT: PROPRANOLOL - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) (b) (4) | 06 Oct 2020 08:02:33 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 06 Oct 2020 08:02:33 |
| Data point term sent to Coder | System | 05 Oct 2020 16:45:26 |
| User entered 'propranolol' | Saysamone Banks (b) (4) (b) (4) | 05 Oct 2020 16:45:02 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:38:11

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered 'No (N)' | Saysamone Banks (b) (4) | 05 Oct 2020 16:45:02 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:38:11

[Indication](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'sinus tachycardia' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 16:45:02 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:38:11

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '40' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 16:45:02 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:38:11

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'mg (mg)' | Saysamone Banks (b) (4) | 05 Oct 2020 16:45:02 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:38:11

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered empty. | Saysamone Banks (b) (4) | 05 Oct 2020 16:45:02 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:38:11

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'once daily (QD)' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 16:45:02 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:38:11

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 16:45:02 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:38:11

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Oral (ORAL)' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 16:45:02 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:38:11

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 16:45:02 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:38:11

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'un Sep 2019' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 16:45:02 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:38:11

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 16:45:02 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:38:11

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Yes (Y)' | Saysamone Banks (b) (4) | 05 Oct 2020 16:45:02 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:38:11

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 16:45:02 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:38:11

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Saysamone Banks (b) (4) | 05 Oct 2020 16:45:02 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:38:11

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Oct 2020 16:45:02 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:38:11

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Oct 2020 16:45:02 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:38:11

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 05 Oct 2020 16:45:02 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:38:11

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|--|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) (b) (4) | 05 Oct 2020 16:48:22 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 05 Oct 2020 16:48:22 |
| Data point term sent to Coder | System | 05 Oct 2020 16:47:33 |
| User entered 'hydrochlorothiazide' | Saysamone Banks (b) (4) (b) (4) | 05 Oct 2020 16:47:13 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:38:11

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered 'No (N)' | Saysamone Banks (b) (4) | 05 Oct 2020 16:47:13 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:38:11

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'hypertension' | Saysamone Banks (b) (4) | 05 Oct 2020 16:47:13 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:38:11

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '25' | Saysamone Banks (b) (4) | 05 Oct 2020 16:47:13 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:38:11

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'mg (mg)' | Saysamone Banks (b) (4) | 05 Oct 2020 16:47:13 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:38:11

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered empty. | Saysamone Banks (b) (4) | 05 Oct 2020 16:47:13 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:38:11

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'once daily (QD)' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 16:47:13 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:38:11

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 16:47:13 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:38:11

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Oral (ORAL)' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 16:47:13 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:38:11

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 16:47:13 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:38:11

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'un Sep 2019' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 16:47:13 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:38:11

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 16:47:13 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:38:11

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Yes (Y)' | Saysamone Banks (b) (4) | 05 Oct 2020 16:47:13 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:38:11

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 16:47:13 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:38:11

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 16:47:13 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:38:11

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Oct 2020 16:47:13 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:38:11

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Oct 2020 16:47:13 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:38:11

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 05 Oct 2020 16:47:13 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:38:11

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 05 Oct 2020 16:55:21 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 05 Oct 2020 16:55:21 |
| Data point term sent to Coder | System | 05 Oct 2020 16:48:34 |
| User entered 'alprazolam' | Saysamone Banks (b) (4) | 05 Oct 2020 16:47:58 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:38:11

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered 'No (N)' | Saysamone Banks (b) (4) | 05 Oct 2020 16:47:58 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:38:11

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'anxiety/insomnia' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 16:47:58 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:38:11

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered '0.5' | Saysamone Banks (b) (4) | 05 Oct 2020 16:47:58 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:38:11

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered 'mg (mg)' | Saysamone Banks (b) (4) | 05 Oct 2020 16:47:58 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:38:11

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered empty. | Saysamone Banks (b) (4) | 05 Oct 2020 16:47:58 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:38:11

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'as needed (PRN)' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 16:47:58 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:38:11

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered empty. | Saysamone Banks (b) (4) | 05 Oct 2020 16:47:58 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:38:11

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Oral (ORAL)' | Saysamone Banks (b) (4) | 05 Oct 2020 16:47:58 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:38:11

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered empty. | Saysamone Banks (b) (4) | 05 Oct 2020 16:47:58 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:38:11

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered 'un Mar 2020' | Saysamone Banks (b) (4) | 05 Oct 2020 16:47:58 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:38:11

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered '0' | Saysamone Banks (b) (4) | 05 Oct 2020 16:47:58 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:38:11

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Saysamone Banks (b) (4) | 05 Oct 2020 16:47:58 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:38:11

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered empty. | Saysamone Banks (b) (4) | 05 Oct 2020 16:47:58 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:38:11

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Saysamone Banks (b) (4) | 05 Oct 2020 16:47:58 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:38:11

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Oct 2020 16:47:58 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:38:11

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Oct 2020 16:47:58 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:38:11

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Oct 2020 16:47:58 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:38:11

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: VENLAFAXINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 05 Oct 2020 16:50:28 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 05 Oct 2020 16:50:28 |
| Data point term sent to Coder | System | 05 Oct 2020 16:49:36 |
| User entered 'venlafaxine' | Saysamone Banks (b) (4) | 05 Oct 2020 16:49:02 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:38:11

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered 'No (N)' | Saysamone Banks (b) (4) | 05 Oct 2020 16:49:02 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:38:11

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'anxiety/depression' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 16:49:02 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:38:11

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '37.5' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 16:49:02 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:38:11

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'mg (mg)' | Saysamone Banks (b) (4) | 05 Oct 2020 16:49:02 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:38:11

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered empty. | Saysamone Banks (b) (4) | 05 Oct 2020 16:49:02 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:38:11

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'twice daily (BID)' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 16:49:02 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:38:11

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered empty. | Saysamone Banks (b) (4) | 05 Oct 2020 16:49:02 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:38:11

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Oral (ORAL)' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 16:49:02 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:38:11

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered empty. | Saysamone Banks (b) (4) | 05 Oct 2020 16:49:02 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:38:11

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'un Mar 2020' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 16:49:02 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:38:11

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Saysamone Banks (b) (4) | 05 Oct 2020 16:49:02 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:38:11

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Yes (Y)' | Saysamone Banks (b) (4) | 05 Oct 2020 16:49:02 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:38:11

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered empty. | Saysamone Banks (b) (4) | 05 Oct 2020 16:49:02 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:38:11

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 16:49:02 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:38:11

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 05 Oct 2020 16:49:02 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:38:11

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Oct 2020 16:49:02 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:38:11

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 05 Oct 2020 16:49:02 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:38:11

Name of Medication

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 05 Oct 2020 18:38:28 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 05 Oct 2020 18:38:28 |
| Data point term sent to Coder | System | 05 Oct 2020 18:37:31 |
| User entered 'melatonin' | Saysamone Banks (b) (4) | 05 Oct 2020 18:37:13 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:38:11

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered 'No (N)' | Saysamone Banks (b) (4) | 05 Oct 2020 18:37:13 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:38:11

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered 'insomnia' | Saysamone Banks (b) (4) | 05 Oct 2020 18:37:13 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:38:11

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '5' | Saysamone Banks (b) (4) | 05 Oct 2020 18:37:13 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:38:11

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered 'mg (mg)' | Saysamone Banks (b) (4) | 05 Oct 2020 18:37:13 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:38:11

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered empty. | Saysamone Banks (b) (4) | 05 Oct 2020 18:37:13 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:38:11

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'as needed (PRN)' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 18:37:13 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:38:11

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered empty. | Saysamone Banks (b) (4) | 05 Oct 2020 18:37:13 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:38:11

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Oral (ORAL)' | Saysamone Banks (b) (4) | 05 Oct 2020 18:37:13 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:38:11

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered empty. | Saysamone Banks (b) (4) | 05 Oct 2020 18:37:13 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:38:11

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'un UNK 2018' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 18:37:13 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:38:11

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered '0' | Saysamone Banks (b) (4) | 05 Oct 2020 18:37:13 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:38:11

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Saysamone Banks (b) (4) | 05 Oct 2020 18:37:13 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:38:11

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered empty. | Saysamone Banks (b) (4) | 05 Oct 2020 18:37:13 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:38:11

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 18:37:13 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:38:11

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Oct 2020 18:37:13 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:38:11

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Oct 2020 18:37:13 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:38:11

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Oct 2020 18:37:13 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:38:11

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 05 Oct 2020 18:50:20 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 05 Oct 2020 18:50:20 |
| Data point term sent to Coder | System | 05 Oct 2020 18:49:11 |
| User entered 'multi vitamin' | Saysamone Banks (b) (4) (b) (4) | 05 Oct 2020 18:48:22 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:38:11

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User closed query 'Per DM CLR: Indication for medication is reportd as SUPPLEMENT, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 26 Jan 2021 17:11:47 |
| Query 'Per DM CLR: Indication for medication is reportd as SUPPLEMENT, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' answered with 'UPDATED FIELD PER INDICATION.' (Site from DM). | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 17:14:57 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 17:14:41 |
| User opened query 'Per DM CLR: Indication for medication is reportd as SUPPLEMENT, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM). | (b) (4), (b) (6) | 23 Nov 2020 17:59:37 |
| User entered 'No (N)' | Saysamone Banks (b) (4) (b) (4) | 05 Oct 2020 18:48:22 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:38:11

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'supplement' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 18:48:22 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:38:11

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '1' | Saysamone Banks (b) (4) | 05 Oct 2020 18:48:22 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:38:11

[Dose unit](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'tablet (TABLET)' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 18:48:22 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:38:11

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered empty. | Saysamone Banks (b) (4) | 05 Oct 2020 18:48:22 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:38:11

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'once daily (QD)' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 18:48:22 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:38:11

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered empty. | Saysamone Banks (b) (4) | 05 Oct 2020 18:48:22 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:38:11

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Oral (ORAL)' | Saysamone Banks (b) (4) | 05 Oct 2020 18:48:22 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:38:11

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 18:48:22 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:38:11

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered 'un Jun 2018' | Saysamone Banks (b) (4) | 05 Oct 2020 18:48:22 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:38:11

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 18:48:22 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:38:11

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Saysamone Banks (b) (4) | 05 Oct 2020 18:48:22 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:38:11

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered empty. | Saysamone Banks (b) (4) | 05 Oct 2020 18:48:22 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:38:11

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 18:48:22 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:38:11

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Oct 2020 18:48:22 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:38:11

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Oct 2020 18:48:22 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:38:11

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 05 Oct 2020 18:48:22 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:38:11

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 05 Oct 2020 18:50:21 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 05 Oct 2020 18:50:21 |
| Data point term sent to Coder | System | 05 Oct 2020 18:49:11 |
| User entered 'fish oil' | Saysamone Banks (b) (4) (b) (4) | 05 Oct 2020 18:49:10 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:38:11

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User closed query 'Per DM CLR: Indication for medication is reportd as SUPPLEMENT, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 26 Jan 2021 17:11:55 |
| Query 'Per DM CLR: Indication for medication is reportd as SUPPLEMENT, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' answered with 'UPDATED FIELD AS INDICATION IS A SUPPLEMENT.' (Site from DM). | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 17:15:28 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 17:15:15 |
| User opened query 'Per DM CLR: Indication for medication is reportd as SUPPLEMENT, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM). | (b) (4), (b) (6) | 23 Nov 2020 18:00:39 |
| User entered 'No (N)' | Saysamone Banks (b) (4) (b) (4) | 05 Oct 2020 18:49:10 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:38:11

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered 'supplement' | Saysamone Banks (b) (4) | 05 Oct 2020 18:49:10 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:38:11

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 800 mg, 1000 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 26 Jan 2021 17:12:05 |
| Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 800 mg, 1000 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'PATIENT DISCLOSED THAT THEY ARE TAKING 1 TABLET. DOSE WAS NOT REPORTED BY PATIENT.' (Site from DM). | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 17:15:57 |
| User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 800 mg, 1000 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM). | (b) (4), (b) (6) | 23 Nov 2020 18:07:13 |
| User entered 'I' | Saysamone Banks (b) (4) (b) (4) | 05 Oct 2020 18:49:10 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:38:11

[Dose unit](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'tablet (TABLET)' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 18:49:10 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:38:11

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered empty. | Saysamone Banks (b) (4) | 05 Oct 2020 18:49:10 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:38:11

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'once daily (QD)' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 18:49:10 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:38:11

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered empty. | Saysamone Banks (b) (4) | 05 Oct 2020 18:49:10 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:38:11

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Oral (ORAL)' | Saysamone Banks (b) (4) | 05 Oct 2020 18:49:10 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:38:11

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered empty. | Saysamone Banks (b) (4) | 05 Oct 2020 18:49:10 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:38:11

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered 'un Jun 2018' | Saysamone Banks (b) (4) | 05 Oct 2020 18:49:10 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:38:11

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 18:49:10 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:38:11

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Saysamone Banks (b) (4) | 05 Oct 2020 18:49:10 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:38:11

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered empty. | Saysamone Banks (b) (4) | 05 Oct 2020 18:49:10 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:38:11

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 18:49:10 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:38:11

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Oct 2020 18:49:10 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:38:11

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Oct 2020 18:49:10 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:38:11

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 05 Oct 2020 18:49:10 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:38:11

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 05 Oct 2020 18:52:18 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 05 Oct 2020 18:52:18 |
| Data point term sent to Coder | System | 05 Oct 2020 18:51:12 |
| User entered 'vitamin d' | Saysamone Banks (b) (4) (b) (4) | 05 Oct 2020 18:50:15 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:38:11

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User closed query 'Per DM CLR: Indication for medication is reportd as SUPPLEMENT, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM). | (b) (4) | |
| Query 'Per DM CLR: Indication for medication is reportd as SUPPLEMENT, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' answered with 'FIELD IS UPDATED AS MEDICATION IS A SUPPLEMENT. THANK YOU.' (Site from DM). | (b) (4), (b) (6) | 26 Jan 2021 05:11:48 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Crystal Mata (b) (4) | 23 Jan 2021 17:24:02 |
| User opened query 'Per DM CLR: Indication for medication is reportd as SUPPLEMENT, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM). | (b) (4) | |
| User entered 'No (N)' | Crystal Mata (b) (4) | 23 Jan 2021 17:16:12 |
| | (b) (4) | |
| | (b) (4), (b) (6) | 23 Nov 2020 18:00:54 |
| | | |
| | Saysamone Banks (b) (4) | 05 Oct 2020 18:50:15 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:38:11

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'supplement' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 18:50:15 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:38:11

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered '5000' | Saysamone Banks (b) (4) | 05 Oct 2020 18:50:15 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:38:11

[Dose unit](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 26 Jan 2021 05:11:52 |
| Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'DOSE UNIT HAS BEEN UPDATED. ' (Site from DM). | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 17:24:51 |
| User entered 'IU (IU)' reason for change: Data Entry Error | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 17:24:32 |
| User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM). | (b) (4), (b) (6) | 23 Nov 2020 18:02:25 |
| User entered 'mg (mg)' | Saysamone Banks (b) (4) (b) (4) | 05 Oct 2020 18:50:15 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:38:11

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered empty. | Saysamone Banks (b) (4) | 05 Oct 2020 18:50:15 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:38:11

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'once daily (QD)' | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 18:50:15 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:38:11

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered empty. | Saysamone Banks (b) (4) | 05 Oct 2020 18:50:15 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:38:11

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Oral (ORAL)' | Saysamone Banks (b) (4) | 05 Oct 2020 18:50:15 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:38:11

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | (b) (4) Saysamone Banks (b) (4) | 05 Oct 2020 18:50:15 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:38:11

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered 'un Jun 2018' | Saysamone Banks (b) (4) | 05 Oct 2020 18:50:15 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:38:11

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered '0' | Saysamone Banks (b) (4) | 05 Oct 2020 18:50:15 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:38:11

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Saysamone Banks (b) (4) | 05 Oct 2020 18:50:15 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:38:11

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| User entered empty. | Saysamone Banks (b) (4) | 05 Oct 2020 18:50:15 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:38:11

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Saysamone Banks (b) (4) | 05 Oct 2020 18:50:15 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:38:11

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Oct 2020 18:50:15 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:38:11

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Oct 2020 18:50:15 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:38:11

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 05 Oct 2020 18:50:15 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:38:11

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:35 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 05 Nov 2020 17:02:40 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 05 Nov 2020 17:02:40 |
| Data point term sent to Coder | System | 02 Nov 2020 22:18:00 |
| User entered 'flu shot' | Saysamone Banks (b) (4) | 02 Nov 2020 22:17:23 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:38:11

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:35 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Saysamone Banks (b) (4) | 02 Nov 2020 22:17:23 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:38:11

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:35 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'flu prevention' | (b) (4) Saysamone Banks (b) (4) | 02 Nov 2020 22:17:23 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:38:11

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:35 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0.5' | (b) (4) Saysamone Banks (b) (4) | 02 Nov 2020 22:17:23 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:38:11

[Dose unit](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:35 |
| User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM). | | 16 Apr 2021 05:52:56 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| | (b) (4) | |
| Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'Updated' (Site from DM). | Saysamone Banks (b) (4) | 08 Apr 2021 02:21:05 |
| | (b) (4) | |
| User entered 'mL (mL)' reason for change: Data Entry Error | Saysamone Banks (b) (4) | 08 Apr 2021 02:20:59 |
| | (b) (4) | |
| User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM). | (b) (4), (b) (6) | 07 Apr 2021 09:45:09 |
| | | |
| User entered 'mg (mg)' | Saysamone Banks (b) (4) | 02 Nov 2020 22:17:23 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:38:11

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:35 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | (b) (4) | |
| | Saysamone Banks (b) (4) | 02 Nov 2020 22:17:23 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:38:11

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:35 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'once (ONCE)' | (b) (4) | |
| | Saysamone Banks (b) (4) | 02 Nov 2020 22:17:23 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:38:11

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:35 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | (b) (4) | |
| | Saysamone Banks (b) (4) | 02 Nov 2020 22:17:23 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:38:11

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:35 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Intramuscular (INTRAMUSCULAR)' | (b) (4) | |
| | Saysamone Banks (b) (4) | 02 Nov 2020 22:17:23 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:38:11

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:35 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | (b) (4) | |
| | Saysamone Banks (b) (4) | 02 Nov 2020 22:17:23 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:38:11

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:35 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '18 Oct 2020' | (b) (4) | |
| | Saysamone Banks (b) (4) | 02 Nov 2020 22:17:23 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:38:11

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:35 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Saysamone Banks (b) (4) | 02 Nov 2020 22:17:23 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:38:11

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:35 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Saysamone Banks (b) (4) | 02 Nov 2020 22:17:23 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:38:11

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:35 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '18 Oct 2020' | (b) (4) | |
| | Saysamone Banks (b) (4) | 02 Nov 2020 22:17:23 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:38:11

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:35 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Saysamone Banks (b) (4) | 02 Nov 2020 22:17:23 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:38:11

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:35 |
| User entered empty. | System | 02 Nov 2020 22:17:23 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:38:11

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:35 |
| User entered empty. | System | 02 Nov 2020 22:17:23 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:38:11

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:35 |
| User entered empty. | System | 02 Nov 2020 22:17:23 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:38:11

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) (b) (4) | 07 Nov 2020 07:41:28 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 07 Nov 2020 07:41:28 |
| Data point term sent to Coder | System | 06 Nov 2020 21:16:04 |
| User entered 'ibuprofen' | maggie Tono (b) (4) (b) (4) | 06 Nov 2020 21:15:45 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:38:11

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | (b) (4) maggie Tono (b) (4) (b) (4) | 06 Nov 2020 21:15:45 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:38:11

[Indication](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'body aches from injection' | maggie Tono (b) (4) | 06 Nov 2020 21:15:45 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:38:11

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '600' | maggie Tono (b) (4) | 06 Nov 2020 21:15:45 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:38:11

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'mg (mg)' | maggie Tono (b) (4) | 06 Nov 2020 21:15:45 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:38:11

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | maggie Tono (b) (4) | 06 Nov 2020 21:15:45 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:38:11

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'twice daily (BID)' | maggie Tono (b) (4) | 06 Nov 2020 21:15:45 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:38:11

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | maggie Tono (b) (4) | 06 Nov 2020 21:15:45 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:38:11

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Oral (ORAL)' | maggie Tono (b) (4) | 06 Nov 2020 21:15:45 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:38:11

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | maggie Tono (b) (4) | 06 Nov 2020 21:15:45 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:38:11

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '5 Nov 2020' | maggie Tono (b) (4) | 06 Nov 2020 21:15:45 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:38:11

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | maggie Tono (b) (4) | 06 Nov 2020 21:15:45 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:38:11

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:38 |
| User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM). User signature succeeded. | (b) (4), (b) (6) | 13 Apr 2021 07:16:01 |
| Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated (Site from DM).' User entered 'No (N)' reason for change: Data Entry Error | John McGettigan (b) (4) (b) (4) (b) (4), (b) (6) | 08 Apr 2021 12:37:15 |
| User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM). User entered 'Yes (Y)' | (b) (4), (b) (6) | 08 Apr 2021 02:41:09 |
| | | 08 Apr 2021 02:40:54 |
| | | 31 Mar 2021 08:24:02 |
| | maggie Tono (b) (4) (b) (4) | 06 Nov 2020 21:15:45 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:38:11

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '18 Nov 2020' reason for change: Data Entry Error | (b) (4) | |
| | (b) (4), (b) (6) | 08 Apr 2021 02:40:54 |
| User entered empty. | maggie Tono (b) (4) | 06 Nov 2020 21:15:45 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:38:11

Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:38 |
| User closed query 'Per DM CLR: Was this medication taken for solicited event? = NO. However, this is a solicited event in the eDiary. Review if this should be updated to Yes. Otherwise, clarify.' (Site from DM). User signature succeeded. | (b) (4) | 13 Apr 2021 07:16:04 |
| Query 'Per DM CLR: Was this medication taken for solicited event? = NO. However, this is a solicited event in the eDiary. Review if this should be updated to Yes. Otherwise, clarify.' answered with 'Updated' (Site from DM). | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Yes (Y)' reason for change: Per Query Resolution | (b) (4) | |
| User opened query 'Per DM CLR: Was this medication taken for solicited event? = NO. However, this is a solicited event in the eDiary. Review if this should be updated to Yes. Otherwise, clarify.' (Site from DM). User entered 'No (N)' | Saysamone Banks (b) (4) | 08 Apr 2021 02:22:04 |
| | (b) (4) | |
| | Saysamone Banks (b) (4) | 08 Apr 2021 02:21:58 |
| | (b) (4) | |
| | (b) (4), (b) (6) | 31 Mar 2021 08:24:07 |
| | | |
| | maggie Tono (b) (4) | 06 Nov 2020 21:15:45 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:38:11

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:38 |
| User entered '2' | System | 06 Nov 2020 21:15:45 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:38:11

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:38 |
| User entered '1' | System | 06 Nov 2020 21:15:45 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:38:11

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:38 |
| User entered '804 (804)' | System | 06 Nov 2020 21:15:45 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:38:11

Name of Medication

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:39 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 24 Jan 2021 20:48:51 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 24 Jan 2021 20:48:51 |
| Data point term sent to Coder | System | 23 Jan 2021 18:42:19 |
| Coding entries removed. | Crystal Mata (b) (4) | 23 Jan 2021 18:41:51 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 17 Nov 2020 07:12:58 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 17 Nov 2020 07:12:58 |
| Data point term sent to Coder | System | 16 Nov 2020 22:22:42 |
| User entered 'levofloxacin' | maggie Tono (b) (4) | 16 Nov 2020 22:21:55 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:38:11

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:39 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | maggie Tono (b) (4) | 16 Nov 2020 22:21:55 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:38:11

[Indication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:39 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. | (b) (4) (b) (4), (b) (6) | 26 Jan 2021 05:12:32 |
| ' (Site from DM). | | |
| Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:42:20 |
| ' answered with 'AE HAS BEEN REPORTED IN ECRF. THANK YOU.' (Site from DM). | | |
| User entered 'RLL PNEUMONIA' reason for change: Data Entry Error | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:41:51 |
| User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. | (b) (4), (b) (6) | 19 Jan 2021 13:15:08 |
| ' (Site from DM). | | |
| User entered 'pneumonia' | maggie Tono (b) (4) (b) (4) | 16 Nov 2020 22:21:55 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:38:11

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:39 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '750' | maggie Tono (b) (4) | 16 Nov 2020 22:21:55 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:38:11

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:39 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'mg (mg)' | (b) (4) maggie Tono (b) (4) (b) (4) | 16 Nov 2020 22:21:55 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:38:11

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:39 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | maggie Tono (b) (4) | 16 Nov 2020 22:21:55 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:38:11

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:39 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'once daily (QD)' | maggie Tono (b) (4) | 16 Nov 2020 22:21:55 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:38:11

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:39 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | maggie Tono (b) (4) | 16 Nov 2020 22:21:55 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:38:11

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:39 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Oral (ORAL)' | maggie Tono (b) (4) | 16 Nov 2020 22:21:55 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:38:11

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:39 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | maggie Tono (b) (4) | 16 Nov 2020 22:21:55 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:38:11

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:39 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User closed query 'Per ETRTR: The start date of the medication is before the start date of RLL PNEUMONIA (18Nov2020). Please clarify. Thanks!' (Site from CRA). | (b) (4) (b) (4), (b) (6) | 25 Mar 2021 23:54:58 |
| Query 'Per ETRTR: The start date of the medication is before the start date of RLL PNEUMONIA (18Nov2020). Please clarify. Thanks!' answered with 'updated ' (Site from CRA). | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:22:17 |
| User entered '18 Nov 2020' reason for change: Data Entry Error | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:21:46 |
| User opened query 'Per ETRTR: The start date of the medication is before the start date of RLL PNEUMONIA (18Nov2020). Please clarify. Thanks!' (Site from CRA). | (b) (4), (b) (6) | 17 Feb 2021 08:06:11 |
| User entered '14 Nov 2020' | maggie Tono (b) (4) (b) (4) | 16 Nov 2020 22:21:55 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:38:11

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:39 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | maggie Tono (b) (4) | 16 Nov 2020 22:21:55 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:38:11

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:39 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 22 Mar 2021 15:21:48 |
| Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'updated ' (Site from DM). | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:22:24 |
| User entered 'No (N)' reason for change: Data Entry Error | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:22:05 |
| User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM). | (b) (4), (b) (6) | 19 Feb 2021 07:52:34 |
| User entered 'Yes (Y)' | maggie Tono (b) (4) (b) (4) | 16 Nov 2020 22:21:55 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:38:11

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:39 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '25 Nov 2020' reason for change: Data Entry Error | (b) (4) | 16 Mar 2021 17:22:05 |
| User entered empty. | Yvonne De Los Reyes | 16 Mar 2021 17:22:05 |
| | (b) (4) | |
| | maggie Tono (b) (4) | 16 Nov 2020 22:21:55 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:38:11

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:39 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | maggie Tono (b) (4) | 16 Nov 2020 22:21:55 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:38:11

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:39 |
| User entered '1' | System | 16 Nov 2020 22:21:55 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:38:11

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:39 |
| User entered '1' | System | 16 Nov 2020 22:21:55 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:38:11

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:39 |
| User entered '804 (804)' | System | 16 Nov 2020 22:21:55 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:38:11

Name of Medication

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:42 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 24 Jan 2021 11:50:50 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 24 Jan 2021 11:50:50 |
| Data point term sent to Coder | System | 23 Jan 2021 18:43:19 |
| Coding entries removed. | Crystal Mata (b) (4) | 23 Jan 2021 18:42:32 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 17 Nov 2020 01:54:50 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 17 Nov 2020 01:54:50 |
| Data point term sent to Coder | System | 16 Nov 2020 22:23:42 |
| User entered 'albuterol inhaler' | maggie Tono (b) (4) | 16 Nov 2020 22:23:28 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:38:11

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:42 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | maggie Tono (b) (4) | 16 Nov 2020 22:23:28 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:38:11

[Indication](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:42 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. | (b) (4) (b) (4), (b) (6) | 26 Jan 2021 05:12:46 |
| ' (Site from DM). | | |
| Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. | Crystal Mata (b) (4) | 23 Jan 2021 18:43:22 |
| ' answered with 'AE HAS BEEN REPORTED IN ECRF. THANK YOU.' (Site from DM). | (b) (4) | |
| User entered 'RLL PNEUMONIA' reason for change: Data Entry Error | Crystal Mata (b) (4) | 23 Jan 2021 18:42:32 |
| User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. | (b) (4), (b) (6) | 19 Jan 2021 13:15:41 |
| ' (Site from DM). | | |
| User entered 'pneumonia' | maggie Tono (b) (4) | 16 Nov 2020 22:23:28 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:38:11

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:42 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '2' | maggie Tono (b) (4) | 16 Nov 2020 22:23:28 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:38:11

[Dose unit](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:42 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'puff (PUFF)' | maggie Tono (b) (4) | 16 Nov 2020 22:23:28 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:38:11

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:42 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | maggie Tono (b) (4) | 16 Nov 2020 22:23:28 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:38:11

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:42 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'as needed (PRN)' | maggie Tono (b) (4) | 16 Nov 2020 22:23:28 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:38:11

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:42 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | maggie Tono (b) (4) | 16 Nov 2020 22:23:28 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:38:11

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:42 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' | maggie Tono (b) (4) | 16 Nov 2020 22:23:28 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:38:11

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:42 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | maggie Tono (b) (4) | 16 Nov 2020 22:23:28 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:38:11

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:42 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User closed query 'Per ETRTR: The start date of the medication is before the start date of RLL PNEUMONIA (18Nov2020). Please clarify. Thanks!' (Site from CRA). | (b) (4) (b) (4), (b) (6) | 25 Mar 2021 23:57:54 |
| Query 'Per ETRTR: The start date of the medication is before the start date of RLL PNEUMONIA (18Nov2020). Please clarify. Thanks!' answered with 'updated' (Site from CRA). | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:23:26 |
| User entered '18 Nov 2020' reason for change: Data Entry Error | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:23:19 |
| User opened query 'Per ETRTR: The start date of the medication is before the start date of RLL PNEUMONIA (18Nov2020). Please clarify. Thanks!' (Site from CRA). | (b) (4), (b) (6) | 17 Feb 2021 08:07:03 |
| User entered '16 Nov 2020' | maggie Tono (b) (4) (b) (4) | 16 Nov 2020 22:23:28 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:38:11

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:42 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | maggie Tono (b) (4) | 16 Nov 2020 22:23:28 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:38:11

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:42 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 22 Mar 2021 15:22:20 |
| Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM). | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:23:31 |
| User entered 'No (N)' reason for change: Data Entry Error | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:23:19 |
| User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM). | (b) (4), (b) (6) | 19 Feb 2021 07:55:58 |
| User entered 'Yes (Y)' | maggie Tono (b) (4) (b) (4) | 16 Nov 2020 22:23:28 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:38:11

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:42 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '23 Nov 2020' reason for change: Data Entry Error | (b) (4) | 16 Mar 2021 17:23:19 |
| User entered empty. | Yvonne De Los Reyes | 16 Mar 2021 17:23:19 |
| | (b) (4) | |
| | maggie Tono (b) (4) | 16 Nov 2020 22:23:28 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:38:11

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:42 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | maggie Tono (b) (4) | 16 Nov 2020 22:23:28 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:38:11

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:42 |
| User entered empty. | System | 16 Nov 2020 22:23:28 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:38:11

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:42 |
| User entered empty. | System | 16 Nov 2020 22:23:28 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:38:11

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:42 |
| User entered empty. | System | 16 Nov 2020 22:23:28 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:38:11

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:46 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) (b) (4) | 17 Nov 2020 02:03:51 |
| 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 Nov 2020 02:03:51 |
| Data point term sent to Coder | System | 16 Nov 2020 22:25:43 |
| User entered 'aspirin' | maggie Tono (b) (4) (b) (4) | 16 Nov 2020 22:24:43 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:38:11

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:46 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | maggie Tono (b) (4) | 16 Nov 2020 22:24:43 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:38:11

[Indication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:46 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. | (b) (4) (b) (4), (b) (6) | 26 Jan 2021 17:13:20 |
| ' (Site from DM). | | |
| Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 18:43:41 |
| ' answered with 'INDICATION IS REPORTED IN AE ECRF. THANK YOU.' (Site from DM). | | |
| User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. | (b) (4), (b) (6) | 19 Jan 2021 13:15:57 |
| ' (Site from DM). | | |
| User entered 'headache from the pneumonia' | maggie Tono (b) (4) (b) (4) | 16 Nov 2020 22:24:43 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:38:11

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:46 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '325' | maggie Tono (b) (4) | 16 Nov 2020 22:24:43 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:38:11

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:46 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'mg (mg)' | (b) (4) maggie Tono (b) (4) (b) (4) | 16 Nov 2020 22:24:43 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:38:11

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:46 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | maggie Tono (b) (4) | 16 Nov 2020 22:24:43 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:38:11

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:46 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'twice daily (BID)' | maggie Tono (b) (4) | 16 Nov 2020 22:24:43 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:38:11

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:46 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | (b) (4) maggie Tono (b) (4) (b) (4) | 16 Nov 2020 22:24:43 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:38:11

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:46 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Oral (ORAL)' | maggie Tono (b) (4) | 16 Nov 2020 22:24:43 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:38:11

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:46 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | maggie Tono (b) (4) | 16 Nov 2020 22:24:43 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:38:11

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:46 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '11 Nov 2020' | maggie Tono (b) (4) | 16 Nov 2020 22:24:43 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:38:11

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:46 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | maggie Tono (b) (4) | 16 Nov 2020 22:24:43 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:38:11

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:46 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4) maggie Tono (b) (4) | 16 Nov 2020 22:28:24 |
| User entered 'Yes (Y)' | (b) (4) maggie Tono (b) (4) | 16 Nov 2020 22:24:43 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:38:11

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:46 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System). | (b) (4) | 16 Nov 2020 22:28:24 |
| User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System). | System | 16 Nov 2020 22:24:43 |
| User entered '13 Nov 2020' | maggie Tono (b) (4) | 16 Nov 2020 22:24:43 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:38:11

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:46 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | maggie Tono (b) (4) | 16 Nov 2020 22:24:43 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:38:11

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:46 |
| User entered '2' | System | 16 Nov 2020 22:24:43 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:38:11

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:46 |
| User entered '1' | System | 16 Nov 2020 22:24:43 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:38:11

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:46 |
| User entered '804 (804)' | System | 16 Nov 2020 22:24:43 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:38:11

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|--|--|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:47 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) (b) (4) | 16 Nov 2020 22:29:48 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 16 Nov 2020 22:29:48 |
| Data point term sent to Coder User entered 'tylenol' | System maggie Tono (b) (4) (b) (4) | 16 Nov 2020 22:29:47 16 Nov 2020 22:29:43 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:38:11

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:47 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | maggie Tono (b) (4) | 16 Nov 2020 22:29:43 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:38:11

[Indication](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:47 |
| User closed query 'Per DM CLR: Please note, there is a medical condition if RLL PNEUMONIA . Please confirm if this Con Med is given for this medical condition during this time frame. Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match' (Site from DM). User signature succeeded. | (b) (4) | 16 Apr 2021 05:53:05 |
| Query 'Per DM CLR: Please note, there is a medical condition if RLL PNEUMONIA . Please confirm if this Con Med is given for this medical condition during this time frame. Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match' answered with 'patient reported tylenol use for headache ' (Site from DM). | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User opened query 'Per DM CLR: Please note, there is a medical condition if RLL PNEUMONIA . Please confirm if this Con Med is given for this medical condition during this time frame. Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match' (Site from DM). | (b) (4) | |
| User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. | Yvonne De Los Reyes (b) (4) | 08 Apr 2021 02:44:41 |
| ' (Site from DM). | | |
| Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. | (b) (4), (b) (6) | 07 Apr 2021 09:54:45 |
| ' answered with 'AE HAS BEEN REPORTED IN ECRFS. THANK YOU.' (Site from DM). | | |
| User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. | (b) (4), (b) (6) | 26 Jan 2021 05:13:00 |
| ' (Site from DM). | | |
| Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. | Crystal Mata (b) (4) | 23 Jan 2021 18:44:07 |
| ' answered with 'AE HAS BEEN REPORTED IN ECRFS. THANK YOU.' (Site from DM). | (b) (4) | |
| User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. | (b) (4), (b) (6) | 19 Jan 2021 13:16:13 |
| ' (Site from DM). | | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:38:11

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------|--------------------------------|----------------------|
| User entered 'headache' | maggie Tono (b) (4) (b) (4) | 16 Nov 2020 22:29:43 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:38:11

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:47 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '500' | maggie Tono (b) (4) | 16 Nov 2020 22:29:43 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:38:11

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:47 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'mg (mg)' | (b) (4) maggie Tono (b) (4) | 16 Nov 2020 22:29:43 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:38:11

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:47 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | maggie Tono (b) (4) | 16 Nov 2020 22:29:43 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:38:11

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:47 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'twice daily (BID)' | maggie Tono (b) (4) | 16 Nov 2020 22:29:43 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:38:11

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:47 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | maggie Tono (b) (4) | 16 Nov 2020 22:29:43 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:38:11

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:47 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Oral (ORAL)' | maggie Tono (b) (4) | 16 Nov 2020 22:29:43 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:38:11

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:47 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | maggie Tono (b) (4) | 16 Nov 2020 22:29:43 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:38:11

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:47 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '10 Nov 2020' | maggie Tono (b) (4) | 16 Nov 2020 22:29:43 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:38:11

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:47 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | maggie Tono (b) (4) | 16 Nov 2020 22:29:43 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:38:11

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:47 |
| User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM). User signature succeeded. | (b) (4) | 13 Apr 2021 07:16:21 |
| Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM). | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4) | |
| User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM). | Yvonne De Los Reyes (b) (4) | 08 Apr 2021 02:59:31 |
| User entered 'Yes (Y)' | Yvonne De Los Reyes (b) (4) | 08 Apr 2021 02:59:19 |
| | (b) (4), (b) (6) | 31 Mar 2021 08:24:26 |
| | maggie Tono (b) (4) | 16 Nov 2020 22:29:43 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:38:11

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:47 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '16 Nov 2020' reason for change: Data Entry Error | (b) (4) | 08 Apr 2021 02:59:19 |
| User entered empty. | Yvonne De Los Reyes | 08 Apr 2021 02:59:19 |
| | (b) (4) | |
| | maggie Tono (b) (4) | 16 Nov 2020 22:29:43 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:38:11

Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:47 |
| User closed query 'Per DM CLR: Was this medication taken for solicited event? = NO. However, this is a solicited event in the eDiary. Review if this should be updated to Yes. Otherwise, clarify.' (Site from DM). | | 13 Apr 2021 07:16:22 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| Query 'Per DM CLR: Was this medication taken for solicited event? = NO. However, this is a solicited event in the eDiary. Review if this should be updated to Yes. Otherwise, clarify.' answered with 'updated ' (Site from DM). | (b) (4) | |
| | Yvonne De Los Reyes | 08 Apr 2021 02:58:26 |
| | (b) (4) | |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Yvonne De Los Reyes | 08 Apr 2021 02:58:21 |
| | (b) (4) | |
| User opened query 'Per DM CLR: Was this medication taken for solicited event? = NO. However, this is a solicited event in the eDiary. Review if this should be updated to Yes. Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6) | 31 Mar 2021 08:24:33 |
| User entered 'No (N)' | maggie Tono (b) (4) | 16 Nov 2020 22:29:43 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:38:11

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:47 |
| User entered '2' | System | 16 Nov 2020 22:29:43 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:38:11

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:47 |
| User entered '1' | System | 16 Nov 2020 22:29:43 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:38:11

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:47 |
| User entered '804 (804)' | System | 16 Nov 2020 22:29:43 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:38:11

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:51 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\202003. | (b) (4) Coder Import (b) (4) | 25 Jan 2021 07:34:01 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003. | Coder Import (b) (4) (b) (4) | 25 Jan 2021 07:34:01 |
| Data point term sent to Coder | System | 23 Jan 2021 19:01:27 |
| User entered 'VANCOMYCIN' | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 19:00:53 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:38:11

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:51 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Crystal Mata (b) (4) | 23 Jan 2021 19:00:53 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:38:11

[Indication](#)

| Audit | User | Time (GMT) |
|------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:51 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'RLL PNEUMONIA' | Crystal Mata (b) (4) | 23 Jan 2021 19:00:53 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:38:11

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:51 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'UNKNOWN' | Crystal Mata (b) (4) | 23 Jan 2021 19:00:53 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:38:11

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:51 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Other (OTHER)' | Crystal Mata (b) (4) | 23 Jan 2021 19:00:53 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:38:11

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:51 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'UNKNOWN' | Crystal Mata (b) (4) | 23 Jan 2021 19:00:53 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:38:11

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:51 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'once daily (QD)' | Crystal Mata (b) (4) | 23 Jan 2021 19:00:53 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:38:11

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:51 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 19:00:53 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:38:11

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:51 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Intravenous (INTRAVENOUS)' | Crystal Mata (b) (4) | 23 Jan 2021 19:00:53 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:38:11

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:51 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 19:00:53 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:38:11

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:51 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '18 Nov 2020' | Crystal Mata (b) (4) | 23 Jan 2021 19:00:53 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:38:11

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:51 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Crystal Mata (b) (4) | 23 Jan 2021 19:00:53 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:38:11

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:51 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Crystal Mata (b) (4) | 23 Jan 2021 19:00:53 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:38:11

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:51 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '23 Nov 2020' | Crystal Mata (b) (4) | 23 Jan 2021 19:00:53 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:38:11

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:51 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Crystal Mata (b) (4) | 23 Jan 2021 19:00:53 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:38:11

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:51 |
| User entered '1' | System | 23 Jan 2021 19:00:53 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:38:11

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:51 |
| User entered '1' | System | 23 Jan 2021 19:00:53 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:38:11

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:58:51 |
| User entered '804 (804)' | System | 23 Jan 2021 19:00:53 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:38:11

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:19 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 24 Jan 2021 20:53:53 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 24 Jan 2021 20:53:53 |
| Data point term sent to Coder | System | 23 Jan 2021 19:02:28 |
| User entered 'METRONIDAZOLE' | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 19:02:20 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:38:11

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:19 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Crystal Mata (b) (4) | 23 Jan 2021 19:02:20 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:38:11

[Indication](#)

| Audit | User | Time (GMT) |
|------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:19 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'RLL PNEUMONIA' | Crystal Mata (b) (4) | 23 Jan 2021 19:02:20 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:38:11

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:19 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'UNKNOWN' | Crystal Mata (b) (4) | 23 Jan 2021 19:02:20 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:38:11

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:19 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'mg (mg)' | (b) (4) Crystal Mata (b) (4) | 23 Jan 2021 19:02:20 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:38:11

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:19 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 19:02:20 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:38:11

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:19 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'once daily (QD)' | Crystal Mata (b) (4) | 23 Jan 2021 19:02:20 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:38:11

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:19 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 19:02:20 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:38:11

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:19 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Oral (ORAL)' | Crystal Mata (b) (4) | 23 Jan 2021 19:02:20 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:38:11

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:19 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 19:02:20 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:38:11

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:19 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '18 Nov 2020' | Crystal Mata (b) (4) | 23 Jan 2021 19:02:20 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:38:11

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:19 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Crystal Mata (b) (4) | 23 Jan 2021 19:02:20 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:38:11

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:19 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Crystal Mata (b) (4) | 23 Jan 2021 19:02:20 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:38:11

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:19 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '23 Nov 2020' | Crystal Mata (b) (4) | 23 Jan 2021 19:02:20 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:38:11

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:19 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Crystal Mata (b) (4) | 23 Jan 2021 19:02:20 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:38:11

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:19 |
| User entered '1' | System | 23 Jan 2021 19:02:20 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:38:11

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:19 |
| User entered '1' | System | 23 Jan 2021 19:02:20 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:38:11

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:19 |
| User entered '804 (804)' | System | 23 Jan 2021 19:02:20 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:38:11

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:20 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, PRODUCT: CEPHALOSPORIN NOS - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 24 Jan 2021 20:10:58 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 24 Jan 2021 20:10:58 |
| Data point term sent to Coder | System | 23 Jan 2021 19:03:28 |
| User entered 'CEPHALOSPORIN' | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 19:03:23 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:38:11

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:20 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Crystal Mata (b) (4) | 23 Jan 2021 19:03:23 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:38:11

[Indication](#)

| Audit | User | Time (GMT) |
|------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:20 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'RLL PNEUMONIA' | Crystal Mata (b) (4) | 23 Jan 2021 19:03:23 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:38:11

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:20 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'UNKNOWN' | Crystal Mata (b) (4) | 23 Jan 2021 19:03:23 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:38:11

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:20 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'mg (mg)' | Crystal Mata (b) (4) | 23 Jan 2021 19:03:23 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:38:11

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:20 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 19:03:23 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:38:11

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:20 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'once daily (QD)' | Crystal Mata (b) (4) | 23 Jan 2021 19:03:23 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:38:11

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:20 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 19:03:23 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:38:11

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:20 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Intravenous (INTRAVENOUS)' | Crystal Mata (b) (4) | 23 Jan 2021 19:03:23 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:38:11

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:20 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 19:03:23 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:38:11

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:20 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '18 Nov 2020' | Crystal Mata (b) (4) | 23 Jan 2021 19:03:23 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:38:11

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:20 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Crystal Mata (b) (4) | 23 Jan 2021 19:03:23 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:38:11

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:20 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Crystal Mata (b) (4) | 23 Jan 2021 19:03:23 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:38:11

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:20 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '23 Nov 2020' | Crystal Mata (b) (4) | 23 Jan 2021 19:03:23 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:38:11

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:20 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Crystal Mata (b) (4) | 23 Jan 2021 19:03:23 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:38:11

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:20 |
| User entered '1' | System | 23 Jan 2021 19:03:23 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:38:11

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:20 |
| User entered '1' | System | 23 Jan 2021 19:03:23 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:38:11

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:20 |
| User entered '804 (804)' | System | 23 Jan 2021 19:03:23 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:38:11

Name of Medication

| Audit | User | Time (GMT) |
|---|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:22 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: MEDICAL GASES, PRODUCT: OXYGEN - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) (b) (4) | 25 Jan 2021 06:54:57 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 25 Jan 2021 06:54:57 |
| Data point term sent to Coder | System | 23 Jan 2021 20:00:54 |
| User entered 'SUPPLEMENT OXYGEN' | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 20:00:32 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:38:11

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:22 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Crystal Mata (b) (4) | 23 Jan 2021 20:00:32 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:38:11

[Indication](#)

| Audit | User | Time (GMT) |
|--------------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:22 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'HYPOXIA AND PNEUMONIA' | Crystal Mata (b) (4) | 23 Jan 2021 20:00:32 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:38:11

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:22 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '2-4' | Crystal Mata (b) (4) | 23 Jan 2021 20:00:32 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:38:11

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:22 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Other (OTHER)' | Crystal Mata (b) (4) | 23 Jan 2021 20:00:32 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:38:11

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:22 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'LITERS' | Crystal Mata (b) (4) | 23 Jan 2021 20:00:32 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:38:11

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:22 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'once daily (QD)' | Crystal Mata (b) (4) | 23 Jan 2021 20:00:32 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:38:11

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:22 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 20:00:32 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:38:11

[Route of administration](#)

| Audit | User | Time (GMT) |
|------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:22 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Nasal (NASAL)' | Crystal Mata (b) (4) | 23 Jan 2021 20:00:32 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:38:11

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:22 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 20:00:32 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:38:11

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:22 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '18 Nov 2020' | Crystal Mata (b) (4) | 23 Jan 2021 20:00:32 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:38:11

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:22 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Crystal Mata (b) (4) | 23 Jan 2021 20:00:32 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:38:11

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:22 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. | (b) (4) (b) (4), (b) (6) | 22 Mar 2021 15:22:38 |
| ' (Site from DM). | | |
| Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:24:24 |
| ' answered with 'updated' (Site from DM). | | |
| User entered 'No (N)' reason for change: Data Entry Error | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:24:17 |
| User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. | (b) (4), (b) (6) | 19 Feb 2021 07:56:51 |
| ' (Site from DM). | | |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 20:00:42 |
| User entered 'No (N)' | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 20:00:32 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:38:11

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:22 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '25 Nov 2020' reason for change: Data Entry Error | (b) (4) | |
| | Yvonne De Los Reyes | 16 Mar 2021 17:24:17 |
| User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System). | (b) (4) | 23 Jan 2021 20:00:42 |
| User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System). | System | 23 Jan 2021 20:00:32 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 20:00:32 |
| | (b) (4) | |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:38:11

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:22 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Crystal Mata (b) (4) | 23 Jan 2021 20:00:32 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:38:11

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:22 |
| User entered '1' | System | 23 Jan 2021 20:00:32 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:38:11

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:22 |
| User entered '1' | System | 23 Jan 2021 20:00:32 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:38:11

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:22 |
| User entered '804 (804)' | System | 23 Jan 2021 20:00:32 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:38:11

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN, PRODUCTSYNONYM: LEVAQUIN - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) (b) (4) | 24 Jan 2021 20:48:51 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 24 Jan 2021 20:48:51 |
| Data point term sent to Coder | System | 23 Jan 2021 20:03:55 |
| User entered 'LEVAQUIN' | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 20:03:34 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:38:11

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Crystal Mata (b) (4) | 23 Jan 2021 20:03:34 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:38:11

[Indication](#)

| Audit | User | Time (GMT) |
|------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'RLL PNEUMONIA' | Crystal Mata (b) (4) | 23 Jan 2021 20:03:34 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:38:11

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '750' | Crystal Mata (b) (4) | 23 Jan 2021 20:03:34 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:38:11

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'mg (mg)' | (b) (4) Crystal Mata (b) (4) | 23 Jan 2021 20:03:34 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:38:11

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 20:03:34 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:38:11

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'once daily (QD)' | Crystal Mata (b) (4) | 23 Jan 2021 20:03:34 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:38:11

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 20:03:34 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:38:11

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Oral (ORAL)' | Crystal Mata (b) (4) | 23 Jan 2021 20:03:34 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:38:11

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 20:03:34 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:38:11

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User closed query 'Per ETRTR: The start date of the medication is before the start date of RLL PNEUMONIA (18Nov2020). Please clarify. Thanks!' (Site from CRA). | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 00:00:14 |
| Query 'Per ETRTR: The start date of the medication is before the start date of RLL PNEUMONIA (18Nov2020). Please clarify. Thanks!' answered with 'updated' (Site from CRA). | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:24:49 |
| User entered '18 Nov 2020' reason for change: Data Entry Error | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:24:37 |
| User opened query 'Per ETRTR: The start date of the medication is before the start date of RLL PNEUMONIA (18Nov2020). Please clarify. Thanks!' (Site from CRA). | (b) (4), (b) (6) | 17 Feb 2021 08:07:43 |
| User entered '10 Nov 2020' | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 20:03:34 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:38:11

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Crystal Mata (b) (4) | 23 Jan 2021 20:03:34 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:38:11

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Crystal Mata (b) (4) | 23 Jan 2021 20:03:34 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:38:11

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '18 Nov 2020' | Crystal Mata (b) (4) | 23 Jan 2021 20:03:34 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:38:11

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:25 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Crystal Mata (b) (4) | 23 Jan 2021 20:03:34 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:38:11

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:25 |
| User entered '1' | System | 23 Jan 2021 20:03:34 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:38:11

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:25 |
| User entered '1' | System | 23 Jan 2021 20:03:34 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:38:11

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:25 |
| User entered '804 (804)' | System | 23 Jan 2021 20:03:34 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:38:11

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:37 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: TRIAZOLE DERIVATIVES, PRODUCT: FLUCONAZOLE - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) (b) (4) | 23 Jan 2021 20:07:04 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 23 Jan 2021 20:07:04 |
| Data point term sent to Coder | System | 23 Jan 2021 20:05:56 |
| User entered 'FLUCONAZOLE' | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 20:05:05 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:38:11

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:37 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Crystal Mata (b) (4) | 23 Jan 2021 20:05:05 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:38:11

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:37 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'VALLEY FEVER' | Crystal Mata (b) (4) | 23 Jan 2021 20:05:05 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:38:11

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:37 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '400' | Crystal Mata (b) (4) | 23 Jan 2021 20:05:05 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:38:11

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:37 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'mg (mg)' | Crystal Mata (b) (4) | 23 Jan 2021 20:05:05 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:38:11

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:37 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 20:05:05 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:38:11

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:37 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'once daily (QD)' | Crystal Mata (b) (4) | 23 Jan 2021 20:05:05 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:38:11

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:37 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 20:05:05 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:38:11

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:37 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Oral (ORAL)' | Crystal Mata (b) (4) | 23 Jan 2021 20:05:05 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:38:11

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:37 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Crystal Mata (b) (4) | 23 Jan 2021 20:05:05 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:38:11

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:37 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '21 Nov 2020' | Crystal Mata (b) (4) | 23 Jan 2021 20:05:05 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:38:11

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:37 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Crystal Mata (b) (4) | 23 Jan 2021 20:05:05 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:38:11

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:37 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' | (b) (4) (b) (4), (b) (6) | 22 Mar 2021 15:22:54 |
| (Site from DM). | | |
| Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:27:05 |
| ' answered with 'updated' (Site from DM). | | |
| User entered 'No (N)' reason for change: Data Entry Error | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:26:50 |
| User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' | (b) (4), (b) (6) | 19 Feb 2021 07:57:19 |
| (Site from DM). | | |
| User entered 'Yes (Y)' | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 20:05:05 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:38:11

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:37 |
| User closed query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM). | | 14 Apr 2021 06:39:39 |
| User signature succeeded. | John McGettigan (b) (4) (b) (4) | 08 Apr 2021 12:37:15 |
| Query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'this is correct per patient ' (Site from DM). | Yvonne De Los Reyes (b) (4) | 08 Apr 2021 03:01:26 |
| User opened query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 02 Apr 2021 08:23:37 |
| Un-reviewed for Data Management. | | 02 Apr 2021 08:23:33 |
| Reviewed for Data Management. | | 02 Apr 2021 08:23:29 |
| User entered '05 Jan 2021' reason for change: Data Entry Error | Yvonne De Los Reyes (b) (4) | 16 Mar 2021 17:26:50 |
| User entered empty. | Crystal Mata (b) (4) (b) (4) | 23 Jan 2021 20:05:05 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:38:11

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:37 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Crystal Mata (b) (4) | 23 Jan 2021 20:05:05 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:38:11

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:37 |
| User entered '1' | System | 23 Jan 2021 20:05:05 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:38:11

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:37 |
| User entered '1' | System | 23 Jan 2021 20:05:05 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:38:11

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:37 |
| User entered '804 (804)' | System | 23 Jan 2021 20:05:05 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:38:11

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) (b) (4) | 14 Mar 2021 21:30:43 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 14 Mar 2021 21:30:43 |
| Data point term sent to Coder | System | 14 Mar 2021 21:30:35 |
| User entered 'ibuprofen' | Damaris Atondo (b) (4) (b) (4) | 14 Mar 2021 21:29:46 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:38:11

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Damaris Atondo (b) (4) | 14 Mar 2021 21:29:46 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:38:11

[Indication](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'sore arm post injection' | Damaris Atondo (b) (4) | 14 Mar 2021 21:29:46 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:38:11

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '400' | Damaris Atondo (b) (4) | 14 Mar 2021 21:29:46 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:38:11

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'mg (mg)' | Damaris Atondo (b) (4) | 14 Mar 2021 21:29:46 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:38:11

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Damaris Atondo (b) (4) | 14 Mar 2021 21:29:46 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:38:11

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'once (ONCE)' | Damaris Atondo (b) (4) | 14 Mar 2021 21:29:46 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:38:11

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Damaris Atondo (b) (4) | 14 Mar 2021 21:29:46 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:38:11

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'Oral (ORAL)' | Damaris Atondo (b) (4) | 14 Mar 2021 21:29:46 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:38:11

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered empty. | Damaris Atondo (b) (4) | 14 Mar 2021 21:29:46 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:38:11

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '2 Mar 2021' | Damaris Atondo (b) (4) | 14 Mar 2021 21:29:46 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:38:11

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered '0' | Damaris Atondo (b) (4) | 14 Mar 2021 21:29:46 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:38:11

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Damaris Atondo (b) (4) | 14 Mar 2021 21:29:46 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:38:11

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:38 |
| User closed query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM). | | 14 Apr 2021 06:39:47 |
| User signature succeeded. | John McGettigan (b) (4) (b) (4) | 08 Apr 2021 12:37:15 |
| Query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'this is correct, patient had sore arm post injection OLV2' (Site from DM). | Yvonne De Los Reyes (b) (4) | 08 Apr 2021 03:04:05 |
| User opened query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 02 Apr 2021 08:23:48 |
| User entered '2 Mar 2021' | Damaris Atondo (b) (4) (b) (4) | 14 Mar 2021 21:29:46 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:38:11

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:38 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 12:37:15 |
| User entered 'No (N)' | Damaris Atondo (b) (4) | 14 Mar 2021 21:29:46 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:38:11

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:38 |
| User entered empty. | System | 14 Mar 2021 21:29:46 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:38:11

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:38 |
| User entered empty. | System | 14 Mar 2021 21:29:46 |

US3192734

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:38:11

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 18:59:38 |
| User entered empty. | System | 14 Mar 2021 21:29:46 |

US3192734

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:38:11

[Were any concomitant procedures performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| | (b) (4) | |
| User entered 'No (N)' | Yvonne De Los Reyes | 09 Oct 2020 23:21:21 |
| | (b) (4) | |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'USA-US097-2021-MRNA-1273-P301000006' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'Yes (Y)' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'No (N)' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'No (N)' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'Yes (Y)' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'No (N)' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'No (N)' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'Yes (Y)' | System | 25 Jan 2021 17:49:58 |
| User entered 'No (N)' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'John' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'McGettigan' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered '5390 E. Erickson Drive' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'Tucson' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'AZ' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered '85712' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'US' | System | 25 Jan 2021 17:50:31 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '5' | System | 09 Apr 2021 14:04:15 |
| User entered '4' | System | 08 Apr 2021 13:06:40 |
| User entered '3' | System | 17 Mar 2021 14:58:41 |
| User entered '2' | System | 01 Feb 2021 19:51:06 |
| User entered '1' | System | 25 Jan 2021 17:50:31 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'USA-US097-2021-MRNA-1273-P301000006' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'Yes (Y)' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'No (N)' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'No (N)' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'Yes (Y)' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'No (N)' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'No (N)' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'Yes (Y)' | System | 25 Jan 2021 17:49:58 |
| User entered 'No (N)' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'John' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'McGettigan' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered '5390 E. Erickson Drive' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'Tucson' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'AZ' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered '85712' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'US' | System | 25 Jan 2021 17:50:31 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '5' | System | 09 Apr 2021 14:04:15 |
| User entered '4' | System | 08 Apr 2021 13:06:40 |
| User entered '3' | System | 17 Mar 2021 14:58:41 |
| User entered '2' | System | 01 Feb 2021 19:51:06 |
| User entered '1' | System | 25 Jan 2021 17:50:31 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:38:11

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '25/Jan/2021 12:50' | (b) (4) System | 25 Jan 2021 17:50:31 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:38:11

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. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'I' | | 25 Jan 2021 17:50:31 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'USA-US097-2021-MRNA-1273-P301000006' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'Yes (Y)' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'No (N)' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'No (N)' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'Yes (Y)' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'No (N)' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'No (N)' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'Yes (Y)' | System | 25 Jan 2021 17:49:58 |
| User entered 'No (N)' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'John' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'McGettigan' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered '5390 E. Erickson Drive' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'Tucson' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'AZ' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered '85712' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'US' | System | 25 Jan 2021 17:50:31 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '5' | System | 09 Apr 2021 14:04:15 |
| User entered '4' | System | 08 Apr 2021 13:06:40 |
| User entered '3' | System | 17 Mar 2021 14:58:41 |
| User entered '2' | System | 01 Feb 2021 19:51:06 |
| User entered '1' | System | 25 Jan 2021 17:50:31 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:38:11

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '01/Feb/2021 14:50' | (b) (4) System | 01 Feb 2021 19:51:06 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:38:11

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. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 17 Mar 2021 14:58:26 |
| User entered 'I' | | 01 Feb 2021 19:51:06 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'USA-US097-2021-MRNA-1273-P301000006' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'Yes (Y)' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'No (N)' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'No (N)' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'Yes (Y)' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'No (N)' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'No (N)' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'Yes (Y)' | System | 25 Jan 2021 17:49:58 |
| User entered 'No (N)' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'John' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'McGettigan' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered '5390 E. Erickson Drive' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'Tucson' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'AZ' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered '85712' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'US' | System | 25 Jan 2021 17:50:31 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '5' | System | 09 Apr 2021 14:04:15 |
| User entered '4' | System | 08 Apr 2021 13:06:40 |
| User entered '3' | System | 17 Mar 2021 14:58:41 |
| User entered '2' | System | 01 Feb 2021 19:51:06 |
| User entered '1' | System | 25 Jan 2021 17:50:31 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:38:11

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered '17/Mar/2021 10:58' | (b) (4) System | 17 Mar 2021 14:58:41 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:38:11

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 08 Apr 2021 13:06:11 |
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| User entered 'I' | (b) (4), (b) (6) | 17 Mar 2021 14:58:41 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'USA-US097-2021-MRNA-1273-P301000006' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'Yes (Y)' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'No (N)' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'No (N)' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'Yes (Y)' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'No (N)' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'No (N)' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'Yes (Y)' | System | 25 Jan 2021 17:49:58 |
| User entered 'No (N)' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'John' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'McGettigan' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered '5390 E. Erickson Drive' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'Tucson' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'AZ' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered '85712' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'US' | System | 25 Jan 2021 17:50:31 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '5' | System | 09 Apr 2021 14:04:15 |
| User entered '4' | System | 08 Apr 2021 13:06:40 |
| User entered '3' | System | 17 Mar 2021 14:58:41 |
| User entered '2' | System | 01 Feb 2021 19:51:06 |
| User entered '1' | System | 25 Jan 2021 17:50:31 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:38:11

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 19:45:24 |
| User entered '08/Apr/2021 08:06' | (b) (4) System | 08 Apr 2021 13:06:40 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:38:11

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Apr 2021 14:05:45 |
| User signature succeeded. | John McGettigan (b) (4) | 08 Apr 2021 19:45:24 |
| User entered 'I' | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 13:06:40 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'USA-US097-2021-MRNA-1273-P301000006' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'Yes (Y)' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'No (N)' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'No (N)' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'Yes (Y)' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'No (N)' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'No (N)' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'Yes (Y)' | System | 25 Jan 2021 17:49:58 |
| User entered 'No (N)' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'John' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'McGettigan' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered '5390 E. Erickson Drive' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'Tucson' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'AZ' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered '85712' | System | 25 Jan 2021 17:47:56 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 03 Apr 2021 14:32:44 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Jan 2021 17:50:35 |
| User entered 'US' | System | 25 Jan 2021 17:50:31 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '5' | System | 09 Apr 2021 14:04:15 |
| User entered '4' | System | 08 Apr 2021 13:06:40 |
| User entered '3' | System | 17 Mar 2021 14:58:41 |
| User entered '2' | System | 01 Feb 2021 19:51:06 |
| User entered '1' | System | 25 Jan 2021 17:50:31 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:38:11

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-------------------------|----------------------|
| User signature succeeded. | John McGettigan (b) (4) | 12 Apr 2021 18:02:51 |
| User entered '09/Apr/2021 10:04' | (b) (4) System | 09 Apr 2021 14:04:15 |

US3192734

Folder: SAE USA-US097-2021-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:38:11

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. | John McGettigan (b) (4) | 12 Apr 2021 18:02:51 |
| Reviewed for Safety. | (b) (4) (d) (4), (b) (6) | 09 Apr 2021 14:05:45 |
| User entered 'I' | | 09 Apr 2021 14:04:15 |