

US3422244 (Prod: Vanderbilt University Medical Center)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:34:32

All time stamps listed in this document are displayed in GMT

US3422244

**Form: Participant Creation**

**Data signed: (b) (4) 05 Mar 2021 18:38:36**

**Generated On: 09 Jun 2021 17:34:32**

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[Participant ID](#)

US3422244

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

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US3422244

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 18:38:39

Generated On: 09 Jun 2021 17:34:32

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|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 09 SEP 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | SCRN                                    |

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US3422244

Folder: Screening

Form: Demographics

Data signed: (b) (4) 05 Mar 2021 18:38:37

Generated On: 09 Jun 2021 17:34:32

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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 05 Mar 2021 18:38:37

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Date of Informed Consent (*dd MMM yyyy*) 9 SEP 2020

Month and Year of Informed Consent (derived) SEP 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes   
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify \_\_\_\_\_

Was this participant screened previously? Yes   
No

If Yes, previous participant number \_\_\_\_\_

Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 05 Mar 2021 18:38:37

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Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 05 Mar 2021 18:38:39

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Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 05 Mar 2021 18:38:39

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|   |  |
|---|--|
| Condition   | OSTEOARTHRITIS   |
| Start date (dd MMM yyyy)                          | 30 JUN 1975  |
| Start date completely unknown                     | False  |
| Condition ongoing at study entry                  | Yes <input checked="" type="radio"/><br>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 1975   |
| Start Year (derived)                              | 1975   |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |



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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 18:38:39

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|   |                                      |
|---|--------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/> |
|   | No <input type="radio"/>             |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 9 SEP 2020                           |
| Time of assessment ( <i>00:00-23:59</i> ) | 10:12 (24 HR)                        |
| Vital Signs Date and Time (derived)       | 9 SEP 2020 10:12                     |
| Height ( <i>xxx.x</i> )                   | 68 in                                |
| Weight ( <i>xxx.x</i> )                   | 132 lb                               |
| BMI ( <i>xxx.x</i> )                      | 20.11250 kg/m <sup>2</sup>           |
| BMI units                                 | KG/M2                                |
| Temperature ( <i>xxx.x</i> )              | ND - Not Done                        |
| Route of measurement                      | Oral <input type="radio"/>           |
|   | Axillary <input type="radio"/>       |
|   | Other <input type="radio"/>          |
| If Other, specify                         |                                      |
| Pulse ( <i>xxx</i> )                      | ND - Not Done                        |
| Pulse units                               | BPM                                  |
| Respiratory Rate ( <i>xxx</i> )           | ND - Not Done                        |
| Respiratory Rate units                    | BREATHS/MIN                          |
| Systolic Blood Pressure ( <i>xxx</i> )    | ND - Not Done                        |
| Systolic Blood Pressure units             | MMHG                                 |
| Diastolic Blood Pressure ( <i>xxx</i> )   | ND - Not Done                        |
| Diastolic Blood Pressure units            | MMHG                                 |
| Height (derived)                          |                                      |
| Weight (derived)                          |                                      |

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 18:38:39

Generated On: 09 Jun 2021 17:34:32

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Was the physical examination performed?

Yes

No

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Date of examination (dd MMM yyyy)

9 SEP 2020

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

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US3422244

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 18:38:39

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes  No

Specify

RETIRED, VOLUNTEERS FOR (b) (6), VERY ACTIVE OUTSIDE THE HOME

**Location and Living Circumstances Risk (check all that apply)**

**No Risk Identified** False

**Resides in Nursing Home or Assisted Living Facility** False

PRODUCTION RELEASE (v12.003 EAB) (1725)

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Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 18:38:39

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 18:38:39

Generated On: 09 Jun 2021 17:34:32

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|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 9 SEP 2020                              |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | VISIT1                                  |

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 05 Mar 2021 18:38:39

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What was the date of randomization? (*dd MMM yyyy*) 09 SEP 2020

What was the participant's randomization number? 190375

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/m<sup>2</sup>) Yes  No

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

Liver Disease Yes  No

Human Immunodeficiency Virus (HIV) infection Yes  No

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Mar 2021 18:38:39

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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 18:38:39

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|   |  |
|---|--|
| Height                                    | ND - Not Done  |
| Weight                                    | ND - Not Done  |
| Timepoint                                 | Pre-Dose <input checked="" type="radio"/><br>Post-Dose <input type="radio"/>                           |
| Were vital signs assessed?                | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                       |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 9 SEP 2020   |
| Time of assessment ( <i>00:00-23:59</i> ) | 10:12 (24 HR)  |
| Vital Signs Date and Time (derived)       | 9 SEP 2020 10:12   |
| Temperature ( <i>xxx.x</i> )              | 98.9 F   |
| Route of measurement                      | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                         | _____  |
| Pulse ( <i>xxx</i> )                      | 85 beats/min   |
| Pulse units                               | BPM  |
| Respiratory Rate ( <i>xxx</i> )           | 16 breaths/min   |
| Respiratory Rate units                    | BREATHS/MIN  |
| Systolic Blood Pressure ( <i>xxx</i> )    | 127 mmHg   |
| Systolic Blood Pressure units             | MMHG   |
| Diastolic Blood Pressure ( <i>xxx</i> )   | 74 mmHg  |
| Diastolic Blood Pressure units            | MMHG   |



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 18:38:39

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|   |   |
|---|---|
| Height                                    | ND - Not Done   |
| Weight                                    | ND - Not Done   |
| Timepoint                                 | Pre-Dose <input type="checkbox"/><br>Post-Dose <input checked="" type="checkbox"/>                              |
| Were vital signs assessed?                | Yes <input checked="" type="checkbox"/><br>No <input type="checkbox"/>  |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 9 SEP 2020  |
| Time of assessment ( <i>00:00-23:59</i> ) | 11:12 (24 HR)   |
| Vital Signs Date and Time (derived)       | 9 SEP 2020 11:12  |
| Temperature ( <i>xxx.x</i> )              | 98.3 F  |
| Route of measurement                      | Oral <input checked="" type="checkbox"/><br>Axillary <input type="checkbox"/><br>Other <input type="checkbox"/> |
| If Other, specify                         | _____   |
| Pulse ( <i>xxx</i> )                      | 81 beats/min  |
| Pulse units                               | BPM   |
| Respiratory Rate ( <i>xxx</i> )           | 16 breaths/min  |
| Respiratory Rate units                    | BREATHS/MIN   |
| Systolic Blood Pressure ( <i>xxx</i> )    | 140 mmHg  |
| Systolic Blood Pressure units             | MMHG  |
| Diastolic Blood Pressure ( <i>xxx</i> )   | 85 mmHg   |
| Diastolic Blood Pressure units            | MMHG  |

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 18:38:39

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Was the physical examination performed?

Yes

No

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Date of examination (*dd MMM yyyy*) \_\_\_\_\_

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 18:38:39

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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) 9 SEP 2020

What was the treatment time? (00:00-23:59) 10:48 (24 HR)

Treatment Date and Time (derived) 9 SEP 2020 10:48

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 18:38:39

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Was the sample collected? Yes  No

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Collection date (*dd MMM yyyy*) 9 SEP 2020

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Collection time (*00:00-23:59*) 10:25 (24 HR)

---

Collection date and time (derived) 9 SEP 2020 10:25

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US3422244

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Mar 2021 18:38:39

Generated On: 09 Jun 2021 17:34:32

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|  |                           |  |                                    |
|--|---------------------------|--|------------------------------------|
| Collection date ( <i>dd MMM yyyy</i> ) |                           |  | 9 SEP 2020                         |
| Lab Test                               | Was the sample collected? | Collection time ( <i>00:00 - 23:59</i> ) | Collection date and time (derived) |
| Nasopharyngeal Swab 1                  | Yes                       | 10:16                                    | 9 SEP 2020 10:16                   |
| Nasopharyngeal Swab 2                  | No                        |  |                                    |

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:38:39

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Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 98.3 °F

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

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

PC Time Stamp 09 SEP 2020 11:12

PC Open Date & Time 09 SEP 2020 11:08

PC Close Date & Time 09 SEP 2020 13:38

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 98.6 °F

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

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

PC Time Stamp 09 SEP 2020 19:40  
PC Open Date & Time 09 SEP 2020 14:33  
PC Close Date & Time 10 SEP 2020 11:59



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:32

**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 <b>TEMPERATURE</b> taken?                            | Yes <input checked="" type="radio"/> |
|  | No <input type="radio"/>             |
| Please record your <b>TEMPERATURE</b> in °F              | 97.8 °F                              |
| Was any <b>MEDICATION TAKEN</b> today for pain or fever? | Yes <input type="radio"/>            |
|  | No <input checked="" type="radio"/>  |

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

|                      |                   |
|----------------------|-------------------|
| PC Time Stamp        | 11 SEP 2020 07:25 |
| PC Open Date & Time  | 10 SEP 2020 12:00 |
| PC Close Date & Time | 11 SEP 2020 11:59 |

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:32

**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 <b>TEMPERATURE</b> taken?                            | Yes <input checked="" type="radio"/> |
|  | No <input type="radio"/>             |
| Please record your <b>TEMPERATURE</b> in °F              | 98.3 °F                              |
| Was any <b>MEDICATION TAKEN</b> today for pain or fever? | Yes <input type="radio"/>            |
|  | No <input checked="" type="radio"/>  |

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

|                      |                   |
|----------------------|-------------------|
| PC Time Stamp        | 11 SEP 2020 21:26 |
| PC Open Date & Time  | 11 SEP 2020 12:00 |
| PC Close Date & Time | 12 SEP 2020 11:59 |

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:32

**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 <b>TEMPERATURE</b> taken?                            | Yes <input checked="" type="radio"/> |
|  | No <input type="radio"/>             |
| Please record your <b>TEMPERATURE</b> in °F              | 97.9 °F                              |
| Was any <b>MEDICATION TAKEN</b> today for pain or fever? | Yes <input type="radio"/>            |
|  | No <input checked="" type="radio"/>  |

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

|                      |                   |
|----------------------|-------------------|
| PC Time Stamp        | 13 SEP 2020 10:38 |
| PC Open Date & Time  | 12 SEP 2020 12:00 |
| PC Close Date & Time | 13 SEP 2020 11:59 |

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:32

**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 <b>TEMPERATURE</b> taken?                            | Yes <input checked="" type="radio"/> |
|  | No <input type="radio"/>             |
| Please record your <b>TEMPERATURE</b> in °F              | 98.2 °F                              |
| Was any <b>MEDICATION TAKEN</b> today for pain or fever? | Yes <input type="radio"/>            |
|  | No <input checked="" type="radio"/>  |

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

|                      |                   |
|----------------------|-------------------|
| PC Time Stamp        | 13 SEP 2020 21:35 |
| PC Open Date & Time  | 13 SEP 2020 12:00 |
| PC Close Date & Time | 14 SEP 2020 11:59 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:32

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

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

|                      |                   |
|----------------------|-------------------|
| PC Time Stamp        | 14 SEP 2020 12:35 |
| PC Open Date & Time  | 14 SEP 2020 12:00 |
| PC Close Date & Time | 15 SEP 2020 11:59 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:32

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

Please confirm reason for pain or fever medication (may select more than one):  
To **TREAT** pain or fever that has already occurred  
To **PREVENT** pain or fever from occurring  
PC Time Stamp  
PC Open Date & Time 15 SEP 2020 12:00  
PC Close Date & Time 16 SEP 2020 11:59

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

**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

09 SEP 2020 11:14

PC Open Date & Time

09 SEP 2020 11:08

PC Close Date & Time

09 SEP 2020 13:38

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

**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

09 SEP 2020 19:42

PC Open Date & Time

09 SEP 2020 14:33

PC Close Date & Time

10 SEP 2020 11:59



US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

DAY 2

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        | 11 SEP 2020 07:26 |
| PC Open Date & Time  | 10 SEP 2020 12:00 |
| PC Close Date & Time | 11 SEP 2020 11:59 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

DAY 3

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        | 11 SEP 2020 21:26 |
| PC Open Date & Time  | 11 SEP 2020 12:00 |
| PC Close Date & Time | 12 SEP 2020 11:59 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:32

**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

13 SEP 2020 10:38

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

DAY 5

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

13 SEP 2020 21:36

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

DAY 6

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

14 SEP 2020 12:35

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

DAY 7

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

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

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

- Yes
- No

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

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

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

**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

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

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

No   
Yes

---

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 09 SEP 2020 11:14 |
| PC Open Date & Time  | 09 SEP 2020 11:08 |
| PC Close Date & Time | 09 SEP 2020 13:38 |

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US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

**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

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

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

No

Yes

---

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 09 SEP 2020 19:41 |
| PC Open Date & Time  | 09 SEP 2020 14:33 |
| PC Close Date & Time | 10 SEP 2020 11:59 |

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US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:32

**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

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:32

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|                      |                              |
|----------------------|------------------------------|
|                      | Yes <input type="checkbox"/> |
| PC Time stamp        | 11 SEP 2020 07:25            |
| PC Open Date & Time  | 10 SEP 2020 12:00            |
| PC Close Date & Time | 11 SEP 2020 11:59            |

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US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:32

**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

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:32

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|                      |                              |
|----------------------|------------------------------|
|                      | Yes <input type="checkbox"/> |
| PC Time stamp        | 11 SEP 2020 21:27            |
| PC Open Date & Time  | 11 SEP 2020 12:00            |
| PC Close Date & Time | 12 SEP 2020 11:59            |

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US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:32

**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

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:32

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|                      |                              |
|----------------------|------------------------------|
|                      | Yes <input type="checkbox"/> |
| PC Time stamp        | 13 SEP 2020 10:39            |
| PC Open Date & Time  | 12 SEP 2020 12:00            |
| PC Close Date & Time | 13 SEP 2020 11:59            |

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US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:32

**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

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:32

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|                      |                              |
|----------------------|------------------------------|
|                      | Yes <input type="checkbox"/> |
| PC Time stamp        | 13 SEP 2020 21:36            |
| PC Open Date & Time  | 13 SEP 2020 12:00            |
| PC Close Date & Time | 14 SEP 2020 11:59            |

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US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:32

**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

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:32

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|                      |                              |
|----------------------|------------------------------|
|                      | Yes <input type="checkbox"/> |
| PC Time stamp        | 14 SEP 2020 12:35            |
| PC Open Date & Time  | 14 SEP 2020 12:00            |
| PC Close Date & Time | 15 SEP 2020 11:59            |

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US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:32

**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

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:32

Yes

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PC Time stamp

---

PC Open Date & Time

15 SEP 2020 12:00

---

PC Close Date & Time

16 SEP 2020 11:59

---

US3422244

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:38:37

Generated On: 09 Jun 2021 17:34:32

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 16 SEP 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3422244

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:38:37

Generated On: 09 Jun 2021 17:34:32

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1



US3422244

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:38:37

Generated On: 09 Jun 2021 17:34:32

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 23 SEP 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3422244

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:38:37

Generated On: 09 Jun 2021 17:34:32

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3422244

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:38:37

Generated On: 09 Jun 2021 17:34:32

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 30 SEP 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3422244

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:38:37

Generated On: 09 Jun 2021 17:34:32

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3422244

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 18:38:39

Generated On: 09 Jun 2021 17:34:32

---

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 7 OCT 2020                              |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | VISIT2                                  |

---

US3422244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 18:38:39

Generated On: 09 Jun 2021 17:34:32

|   |   |
|---|---|
| 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 ( <i>dd MMM yyyy</i> ) | 7 OCT 2020                                |
| Time of assessment ( <i>00:00-23:59</i> ) | 11:09 (24 HR)                             |
| Vital Signs Date and Time (derived)       | 7 OCT 2020 11:09                          |
| Temperature ( <i>xxx.x</i> )              | 98.3 F                                    |
| Route of measurement                      | Oral <input checked="" type="radio"/>     |
|   | Axillary <input type="radio"/>            |
|   | Other <input type="radio"/>               |
| If Other, specify _____                   |   |
| Pulse ( <i>xxx</i> )                      | 72 beats/min                              |
| Pulse units                               | BPM                                       |
| Respiratory Rate ( <i>xxx</i> )           | 16 breaths/min                            |
| Respiratory Rate units                    | BREATHS/MIN                               |
| Systolic Blood Pressure ( <i>xxx</i> )    | 115 mmHg                                  |
| Systolic Blood Pressure units             | MMHG                                      |
| Diastolic Blood Pressure ( <i>xxx</i> )   | 71 mmHg                                   |
| Diastolic Blood Pressure units            | MMHG                                      |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 18:38:39

Generated On: 09 Jun 2021 17:34:32

|   |  |
|---|--|
| 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 ( <i>dd MMM yyyy</i> ) | 7 OCT 2020                                 |
| Time of assessment ( <i>00:00-23:59</i> ) | 12:06 (24 HR)                              |
| Vital Signs Date and Time (derived)       | 7 OCT 2020 12:06                           |
| Temperature ( <i>xxx.x</i> )              | 98.1 F                                     |
| Route of measurement                      | Oral <input checked="" type="radio"/>      |
|   | Axillary <input type="radio"/>             |
|   | Other <input type="radio"/>                |
| If Other, specify _____                   |  |
| Pulse ( <i>xxx</i> )                      | 83 beats/min                               |
| Pulse units                               | BPM  |
| Respiratory Rate ( <i>xxx</i> )           | 14 breaths/min                             |
| Respiratory Rate units                    | BREATHS/MIN                                |
| Systolic Blood Pressure ( <i>xxx</i> )    | 127 mmHg                                   |
| Systolic Blood Pressure units             | MMHG                                       |
| Diastolic Blood Pressure ( <i>xxx</i> )   | 76 mmHg                                    |
| Diastolic Blood Pressure units            | MMHG                                       |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 18:38:39

Generated On: 09 Jun 2021 17:34:32

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

7 OCT 2020

---

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

---



US3422244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 18:38:39

Generated On: 09 Jun 2021 17:34:32

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) 7 OCT 2020

What was the treatment time? (00:00-23:59) 11:36 (24 HR)

Treatment Date and Time (derived) 7 OCT 2020 11:36

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

US3422244

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 18:38:39

Generated On: 09 Jun 2021 17:34:32

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 7 OCT 2020

---

Collection time (*00:00-23:59*) 11:15 (24 HR)

---

Collection date and time (derived) 7 OCT 2020 11:15

---

US3422244

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Mar 2021 18:38:39

Generated On: 09 Jun 2021 17:34:32

---

|  |                           |  |                                    |
|--|---------------------------|--|------------------------------------|
| Collection date ( <i>dd MMM yyyy</i> ) |                           |  | 7 OCT 2020                         |
| Lab Test                               | Was the sample collected? | Collection time ( <i>00:00 - 23:59</i> ) | Collection date and time (derived) |
| Nasopharyngeal Swab 1                  | Yes                       | 11:12                                    | 7 OCT 2020 11:12                   |
| Nasopharyngeal Swab 2                  | No                        |  |                                    |

---

US3422244

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:38:39

Generated On: 09 Jun 2021 17:34:32

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 98.1 °F

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

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

PC Time Stamp 07 OCT 2020 12:09

PC Open Date & Time 07 OCT 2020 11:56

PC Close Date & Time 07 OCT 2020 14:26

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 97.6 °F

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

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

PC Time Stamp 07 OCT 2020 21:25  
PC Open Date & Time 07 OCT 2020 15:21  
PC Close Date & Time 08 OCT 2020 11:59

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:32

**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 <b>TEMPERATURE</b> taken?                            | Yes <input checked="" type="radio"/> |
|  | No <input type="radio"/>             |
| Please record your <b>TEMPERATURE</b> in °F              | 98.1 °F                              |
| Was any <b>MEDICATION TAKEN</b> today for pain or fever? | Yes <input type="radio"/>            |
|  | No <input checked="" type="radio"/>  |

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

|                      |                   |
|----------------------|-------------------|
| PC Time Stamp        | 08 OCT 2020 15:37 |
| PC Open Date & Time  | 08 OCT 2020 12:00 |
| PC Close Date & Time | 09 OCT 2020 11:59 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:32

**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 <b>TEMPERATURE</b> taken?                            | Yes <input checked="" type="radio"/> |
|  | No <input type="radio"/>             |
| Please record your <b>TEMPERATURE</b> in °F              | 97.9 °F                              |
| Was any <b>MEDICATION TAKEN</b> today for pain or fever? | Yes <input type="radio"/>            |
|  | No <input checked="" type="radio"/>  |

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

|                      |                   |
|----------------------|-------------------|
| PC Time Stamp        | 10 OCT 2020 04:35 |
| PC Open Date & Time  | 09 OCT 2020 12:00 |
| PC Close Date & Time | 10 OCT 2020 11:59 |



US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:32

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

Please confirm reason for pain or fever medication (may select more than one):  
To **TREAT** pain or fever that has already occurred  
To **PREVENT** pain or fever from occurring  
PC Time Stamp  
PC Open Date & Time 10 OCT 2020 12:00  
PC Close Date & Time 11 OCT 2020 11:59

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:32

**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 <b>TEMPERATURE</b> taken?                            | Yes <input checked="" type="radio"/> |
|  | No <input type="radio"/>             |
| Please record your <b>TEMPERATURE</b> in °F              | 98.2 °F                              |
| Was any <b>MEDICATION TAKEN</b> today for pain or fever? | Yes <input type="radio"/>            |
|  | No <input checked="" type="radio"/>  |

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

|                      |                   |
|----------------------|-------------------|
| PC Time Stamp        | 11 OCT 2020 17:31 |
| PC Open Date & Time  | 11 OCT 2020 12:00 |
| PC Close Date & Time | 12 OCT 2020 11:59 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:32

**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 <b>TEMPERATURE</b> taken?                            | Yes <input checked="" type="radio"/> |
|  | No <input type="radio"/>             |
| Please record your <b>TEMPERATURE</b> in °F              | 97.9 °F                              |
| Was any <b>MEDICATION TAKEN</b> today for pain or fever? | Yes <input type="radio"/>            |
|  | No <input checked="" type="radio"/>  |

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

|                      |                   |
|----------------------|-------------------|
| PC Time Stamp        | 12 OCT 2020 13:50 |
| PC Open Date & Time  | 12 OCT 2020 12:00 |
| PC Close Date & Time | 13 OCT 2020 11:59 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:32

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

Please confirm reason for pain or fever medication (may select more than one):  
To **TREAT** pain or fever that has already occurred  
To **PREVENT** pain or fever from occurring  
PC Time Stamp  
PC Open Date & Time 13 OCT 2020 12:00  
PC Close Date & Time 14 OCT 2020 11:59

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

**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

07 OCT 2020 12:09

PC Open Date & Time

07 OCT 2020 11:56

PC Close Date & Time

07 OCT 2020 14:26

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

**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

07 OCT 2020 21:24

PC Open Date & Time

07 OCT 2020 15:21

PC Close Date & Time

08 OCT 2020 11:59

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

DAY 2

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        | 08 OCT 2020 15:37 |
| PC Open Date & Time  | 08 OCT 2020 12:00 |
| PC Close Date & Time | 09 OCT 2020 11:59 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

DAY 3

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        | 10 OCT 2020 04:35 |
| PC Open Date & Time  | 09 OCT 2020 12:00 |
| PC Close Date & Time | 10 OCT 2020 11:59 |



US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

DAY 4

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

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

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

- Yes
- No

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

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

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

DAY 5

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        | 11 OCT 2020 17:32 |
| PC Open Date & Time  | 11 OCT 2020 12:00 |
| PC Close Date & Time | 12 OCT 2020 11:59 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

DAY 6

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

12 OCT 2020 13:51

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

DAY 7

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

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

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

- Yes
- No

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

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

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

**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

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

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

No

Yes

PC Time stamp

PC Open Date & Time

07 OCT 2020 11:56

PC Close Date & Time

07 OCT 2020 14:26

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

**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

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

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

No

Yes

---

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 07 OCT 2020 21:26 |
| PC Open Date & Time  | 07 OCT 2020 15:21 |
| PC Close Date & Time | 08 OCT 2020 11:59 |

---



US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:32

**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

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:32

---

|                      |                              |
|----------------------|------------------------------|
|                      | Yes <input type="checkbox"/> |
| PC Time stamp        | 08 OCT 2020 15:38            |
| PC Open Date & Time  | 08 OCT 2020 12:00            |
| PC Close Date & Time | 09 OCT 2020 11:59            |

---

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:32

**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

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:32

---

|                      |                              |
|----------------------|------------------------------|
|                      | Yes <input type="checkbox"/> |
| PC Time stamp        | 10 OCT 2020 04:36            |
| PC Open Date & Time  | 09 OCT 2020 12:00            |
| PC Close Date & Time | 10 OCT 2020 11:59            |

---

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:32

**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

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:32

Yes

---

PC Time stamp

---

PC Open Date & Time

10 OCT 2020 12:00

---

PC Close Date & Time

11 OCT 2020 11:59

---

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:32

**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

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:32

---

|                      |                              |
|----------------------|------------------------------|
|                      | Yes <input type="checkbox"/> |
| PC Time stamp        | 11 OCT 2020 17:32            |
| PC Open Date & Time  | 11 OCT 2020 12:00            |
| PC Close Date & Time | 12 OCT 2020 11:59            |

---



US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:32

**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

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:32

---

|                      |                              |
|----------------------|------------------------------|
|                      | Yes <input type="checkbox"/> |
| PC Time stamp        | 12 OCT 2020 13:51            |
| PC Open Date & Time  | 12 OCT 2020 12:00            |
| PC Close Date & Time | 13 OCT 2020 11:59            |

---

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:32

**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

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:32

Yes

---

PC Time stamp

---

PC Open Date & Time

13 OCT 2020 12:00

---

PC Close Date & Time

14 OCT 2020 11:59

---

US3422244

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:38:37

Generated On: 09 Jun 2021 17:34:32

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 14 OCT 2020

---

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

---

Comments

---

*If Contact Not Made, please provide Comments*

---

US3422244

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:38:37

Generated On: 09 Jun 2021 17:34:32

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3422244

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:38:37

Generated On: 09 Jun 2021 17:34:32

---

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*

---

---

US3422244

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:38:37

Generated On: 09 Jun 2021 17:34:32

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1



US3422244

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:38:37

Generated On: 09 Jun 2021 17:34:32

---

Was Contact Attempted? Yes   
No

---

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

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3422244

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:38:37

Generated On: 09 Jun 2021 17:34:32

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3422244

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 18:38:39

Generated On: 09 Jun 2021 17:34:32

---

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 4 NOV 2020                              |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | VISIT3                                  |

---

US3422244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 18:38:39

Generated On: 09 Jun 2021 17:34:32

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) \_\_\_\_\_

US3422244

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 18:38:39

Generated On: 09 Jun 2021 17:34:32

---

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.*

---

US3422244

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 18:38:39

Generated On: 09 Jun 2021 17:34:32

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 4 NOV 2020

---

Collection time (*00:00-23:59*) 13:35 (24 HR)

---

Collection date and time (derived) 4 NOV 2020 13:35

---

US3422244

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:38:39

Generated On: 09 Jun 2021 17:34:32

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3422244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

| TIMEPOINT   | DAY 64   |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><br>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"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Date and time of submission   | 09 NOV 2020 10:43:37   |
| Patient Cloud Open Date & Time  | 09 NOV 2020 00:01  |
| Patient Cloud Close Date & Time   | 13 NOV 2020 23:59  |



US3422244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

| TIMEPOINT   | DAY 71   |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><br>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"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Date and time of submission   | 16 NOV 2020 10:58:31   |
| Patient Cloud Open Date & Time  | 16 NOV 2020 00:01  |
| Patient Cloud Close Date & Time   | 20 NOV 2020 23:59  |

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

| 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"/><br>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"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Date and time of submission   | 20 NOV 2020 17:15:04   |
| Patient Cloud Open Date & Time  | 20 NOV 2020 00:01  |
| Patient Cloud Close Date & Time   | 24 NOV 2020 23:59  |

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

| TIMEPOINT   | DAY 82   |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><br>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"/><br>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 NOV 2020 09:11:44   |
| Patient Cloud Open Date & Time  | 27 NOV 2020 00:01  |
| Patient Cloud Close Date & Time   | 01 DEC 2020 23:59  |

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

**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

Yes

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

No

Yes

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

Date and time of submission 05 DEC 2020 12:10:00

Patient Cloud Open Date & Time 04 DEC 2020 00:01

Patient Cloud Close Date & Time 08 DEC 2020 23:59

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

| 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"/><br>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"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Date and time of submission   | 14 DEC 2020 13:15:31   |
| Patient Cloud Open Date & Time  | 11 DEC 2020 00:01  |
| Patient Cloud Close Date & Time   | 15 DEC 2020 23:59  |

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

| TIMEPOINT   | DAY 103  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><br>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"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Date and time of submission   | 19 DEC 2020 17:34:52   |
| Patient Cloud Open Date & Time  | 18 DEC 2020 00:01  |
| Patient Cloud Close Date & Time   | 22 DEC 2020 23:59  |

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

| TIMEPOINT   | DAY 110  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><br>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"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Date and time of submission   | 26 DEC 2020 10:07:23   |
| Patient Cloud Open Date & Time  | 25 DEC 2020 00:01  |
| Patient Cloud Close Date & Time   | 29 DEC 2020 23:59  |

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

| TIMEPOINT   | DAY 117  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><br>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"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Date and time of submission   | 01 JAN 2021 09:13:07   |
| Patient Cloud Open Date & Time  | 01 JAN 2021 00:01  |
| Patient Cloud Close Date & Time   | 05 JAN 2021 23:59  |



US3422244

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:34:32

---

| 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 |
|---|--|---------------------------|
| <hr/>   |  |                           |
| <hr/>   |  |                           |

US3422244

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:38:37

Generated On: 09 Jun 2021 17:34:32

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 2 DEC 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3422244

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:38:37

Generated On: 09 Jun 2021 17:34:32

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3422244

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:32

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* \_\_\_\_\_

US3422244

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:32

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

---

---

US3422244

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:34:32

---

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

---

US3422244

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:34:32

---

Generate Next COVID-19 Assessment

Yes

No

---

US3422244

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

Form: Visit Date

Generated On: 09 Jun 2021 17:34:32

---

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 \_\_\_\_\_



US3422244

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

Form: Unblinding

Generated On: 09 Jun 2021 17:34:32

Date of updated informed consent (*dd MMM yyyy*) \_\_\_\_\_

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study \_\_\_\_\_

Was the participant unblinded? Yes   
No

Under what version of the Protocol was the Participant unblinded? Amendment 5   
Amendment 6 or later

Date of unblinding (*dd MMM yyyy*) \_\_\_\_\_

Participant randomization assignment mRNA-1273   
Placebo

Actual Dose 1 mRNA-1273   
Placebo   
Not Administered

Actual Dose 2 mRNA-1273   
Placebo   
Not Administered

Will participant receive mRNA-1273? Yes   
No

Placebo Only Flag \_\_\_\_\_

Continuing with mRNA-1273 \_\_\_\_\_

US3422244

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:32

Was the sample collected? Yes   
No

Collection date (*dd MMM yyyy*) \_\_\_\_\_

Collection time (*00:00-23:59*) \_\_\_\_\_

Collection date and time (derived) \_\_\_\_\_

US3422244

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:34:32

Was the sample collected? Yes   
No

Collection date (*dd MMM yyyy*) \_\_\_\_\_

Collection time (*00:00 - 23:59*) \_\_\_\_\_

Collection Date and Time (derived) \_\_\_\_\_

US3422244

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 05 Mar 2021 18:38:36

Generated On: 09 Jun 2021 17:34:32

---

Did the participant experience any adverse events?

Yes

No

---

If Yes, enter details on the Adverse Events form.

---

US3422244

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Mar 2021 13:36:56

Generated On: 09 Jun 2021 17:34:32

AEID USA-US082-2021-MRNA-1273-P30  
1000004

Adverse event CARDIAC ARREST

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) 03 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes   
No

If not Ongoing, end date (dd MMM yyyy) 03 JAN 2021

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 True

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

US3422244

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Mar 2021 13:36:56

Generated On: 09 Jun 2021 17:34:32

---

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   
Related   
Not Applicable

---

Relationship to Study Procedure Not Related   
Related   
Not Applicable

---

Action taken with investigational product None   
Dose Delayed   
Investigational Product   
Withdrawn   
Not Applicable

---

Other action taken (check all that apply)

---

None True

---

Concomitant Medication False

---

Concomitant Procedure False

---

Outcome Fatal   
Not Recovered/Not Resolved   
Recovered/Resolved   
Recovered/Resolved with   
Sequelae   
Recovering/Resolving   
Unknown

---

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: \_\_\_\_\_

Narrative

US3422244

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Mar 2021 13:36:56

Generated On: 09 Jun 2021 17:34:32

---

PARTICIPANT FOUND  
DECEASED FROM PRESUMED  
CARDIAC ARREST BY SPOUSE.  
TOXICOLOGY AND AUTOPSY  
REPORT PENDING. NO  
MEDICAL RECORDS  
AVAILABLE SINCE  
PARTICIPANT DIED AT HOME.  
LAST CONTACT VIA E-DIARY  
DONE FROM PARTICIPANT WAS  
01JAN2021 AND REPORTED NO  
ISSUES.

---

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

---

---

US3422244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Mar 2021 18:38:36

Generated On: 09 Jun 2021 17:34:32

---

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

Yes

No

---

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

---



US3422244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Mar 2021 18:38:36

Generated On: 09 Jun 2021 17:34:32

Name of Medication GABAPENTIN

Prophylaxis Yes   
No

Indication OSTEOARTHRITIS

Dose per administration 300

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

US3422244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Mar 2021 18:38:36

Generated On: 09 Jun 2021 17:34:32

---

|  |                          |                          |
|--|--------------------------|--------------------------|
|  | 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*) \_\_\_\_\_ 01 JAN 2020

---

Start date completely unknown \_\_\_\_\_ False

---

Ongoing? \_\_\_\_\_ Yes

\_\_\_\_\_ No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? \_\_\_\_\_ Yes

\_\_\_\_\_ No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) \_\_\_\_\_ 802

\_\_\_\_\_ 803

\_\_\_\_\_ 804

US3422244

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Mar 2021 18:38:36

Generated On: 09 Jun 2021 17:34:32

---

Were any concomitant procedures performed?

Yes

No

---

If yes, please complete Concomitant Procedures form.

---

US3422244

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:34:32

---

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

---

US3422244

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 05 Mar 2021 18:38:36

Generated On: 09 Jun 2021 17:34:32

Date of study discontinuation/completion (*dd MMM yyyy*) 03 JAN 2021

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*) 3 JAN 2021

Was autopsy performed?

Yes

No

Unknown

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 05 Mar 2021 18:38:36

Generated On: 09 Jun 2021 17:34:32

|  |  |
|--|--|
| SAEID  | USA-US082-2021-MRNA-1273-P301000004                              |
| Serious  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Life threatening   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity             | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                             | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event                                | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Investigator's First Name                                      | CLARENCE   |
| Investigator's Last Name                                       | CREECH   |
| Site Address: Street   | CCC-5311 MCN   |
| Site Address: City   | NASHVILLE  |
| Site Address: State  | TN   |
| Site Address: Postal Code                                      | 37027  |
| Investigator Country   | US   |
| E2B Transmit Flag (Derived/Hidden)                             | 2  |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 05 Mar 2021 18:38:36

Generated On: 09 Jun 2021 17:34:32

|  |  |
|--|--|
| SAEID  | USA-US082-2021-MRNA-1273-P301000004                              |
| Serious  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Life threatening   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Investigator's First Name  | CLARENCE   |
| Investigator's Last Name   | CREECH   |
| Site Address: Street   | CCC-5311 MCN   |
| Site Address: City   | NASHVILLE  |
| Site Address: State  | TN   |
| Site Address: Postal Code  | 37027  |
| Investigator Country   | US   |
| E2B Transmit Flag (Derived/Hidden)   | 2  |
| Date of submission (Pre-filled from custom function)   | 22/JAN/2021 10:46  |
| <b>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.</b> | True   |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 05 Mar 2021 18:38:36

Generated On: 09 Jun 2021 17:34:32

|  |  |
|--|--|
| SAEID  | USA-US082-2021-MRNA-1273-P301000004                              |
| Serious  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Life threatening   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Investigator's First Name  | CLARENCE   |
| Investigator's Last Name   | CREECH   |
| Site Address: Street   | CCC-5311 MCN   |
| Site Address: City   | NASHVILLE  |
| Site Address: State  | TN   |
| Site Address: Postal Code  | 37027  |
| Investigator Country   | US   |
| E2B Transmit Flag (Derived/Hidden)   | 2  |
| Date of submission (Pre-filled from custom function)   | 04/FEB/2021 12:37  |
| <b>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.</b> | True   |



Audit

US3422244 (Prod: Vanderbilt University Medical Center)

**US3422244**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 17:34:32**

[Participant ID](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)                     | 05 Mar 2021 18:38:37 |
| User entered 'US3422244'  | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 09 Sep 2020 15:09:41 |

US3422244

Form: Participant Creation

Generated On: 09 Jun 2021 17:34:32

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |

US3422244

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:34:32

[Was this visit performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:40 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 09 Sep 2020 15:53:02 |

US3422244

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:34:32

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

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 27 Apr 2021 22:08:20 |
| User signature succeeded.  | Clarence Creech (b) (4)                     | 05 Mar 2021 18:38:40 |
| User entered '09 SEP 2020' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 09 Sep 2020 15:09:43 |

US3422244

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:34:32

[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 22:08:20 |
| User signature succeeded.      | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:40 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>(b) (4), (b) (6) | 09 Sep 2020 15:53:02 |

US3422244

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:34:32

[Folder OID](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered 'SCRN' | System           | 09 Sep 2020 15:53:02 |

US3422244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:32

Date of Birth (MMM yyyy)

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 27 Apr 2021 22:08:20 |
| User signature succeeded.  | Clarence Creech (b) (4)                     | 05 Mar 2021 18:38:37 |
| User entered (b) (6) 1955' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 09 Sep 2020 15:09:44 |



US3422244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:32

[Age](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| User entered '65'         | (b) (4)<br>(b) (4), (b) (6) | 09 Sep 2020 15:52:54 |

US3422244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:32

[Age Units](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered 'YEARS' | System           | 09 Sep 2020 15:52:54 |

US3422244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:32

[Age \(Derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered '65' | System           | 09 Sep 2020 15:51:57 |

US3422244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:32

[Sex](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| User entered 'Male (M)'   | (b) (4)<br>(b) (4), (b) (6) | 09 Sep 2020 15:52:54 |

US3422244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:32

[Ethnicity](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded.                                      | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | (b) (4)<br>(b) (4), (b) (6) | 09 Sep 2020 15:52:54 |

US3422244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:32

White

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| User entered '1'          | (b) (4)<br>(b) (4), (b) (6) | 09 Sep 2020 15:52:54 |

US3422244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:32

[Black](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 09 Sep 2020 15:52:54 |

US3422244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:32

[Asian](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 09 Sep 2020 15:52:54 |



US3422244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:32

[American Indian or Alaska Native](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 09 Sep 2020 15:52:54 |

US3422244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:32

[Native Hawaiian or other Pacific Islander](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 09 Sep 2020 15:52:54 |

US3422244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:32

[Other](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 09 Sep 2020 15:52:54 |

US3422244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:32

If race is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 09 Sep 2020 15:52:54 |

US3422244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:32

Unknown

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 09 Sep 2020 15:52:54 |

US3422244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:32

[Not reported](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 09 Sep 2020 15:52:54 |

US3422244

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:32

Date of Informed Consent (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| User entered '9 Sep 2020' | (b) (4)<br>(b) (4), (b) (6) | 09 Sep 2020 15:51:57 |

US3422244

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:32

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered 'Sep 2020' | System           | 09 Sep 2020 15:51:57 |



US3422244

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:32

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered '2020' | System           | 09 Sep 2020 15:51:57 |

US3422244

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:32

[Protocol Version](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded.      | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| User entered 'Amendment 3 (3)' | (b) (4)<br>(b) (4), (b) (6) | 09 Sep 2020 15:51:57 |

US3422244

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:32

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 09 Sep 2020 15:51:57 |

US3422244

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:32

If No, indicate reason for screen fail

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 09 Sep 2020 15:51:57 |

US3422244

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:32

If reason for screen fail is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 09 Sep 2020 15:51:57 |

US3422244

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:32

[Was this participant screened previously?](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded.                                 | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4)<br>(b) (4), (b) (6) | 09 Sep 2020 15:52:42 |
| User entered 'Yes (Y)'                                    | (b) (4), (b) (6)            | 09 Sep 2020 15:51:57 |

US3422244

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:32

If Yes, previous participant number

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded.  | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| User closed query 'Was this participant screened previously is Yes, however previous participant number is missing. Please provide.' (Site from System). | (b) (4)<br>System                | 09 Sep 2020 15:52:42 |
| User opened query 'Was this participant screened previously is Yes, however previous participant number is missing. Please provide.' (Site from System). | System                           | 09 Sep 2020 15:51:57 |
| User entered empty.  | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 09 Sep 2020 15:09:43 |

US3422244

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:32

[Enrollment Trigger](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered '1'  | System           | 09 Sep 2020 15:51:57 |



US3422244

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:34:32

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 09 Sep 2020 15:51:39 |

US3422244

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:34:32

[Were any significant conditions reported?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered 'Yes (Y)'    | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:07:07 |

US3422244

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:32

Condition

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)        | 27 Apr 2021 22:08:20 |
| User signature succeeded.  | Clarence Creech (b) (4) | 05 Mar 2021 18:38:40 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\23.0.   | Coder Import (b) (4)    | 11 Nov 2020 20:10:36 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.  | Coder Import (b) (4)    | 11 Nov 2020 20:10:36 |
| Data point term sent to Coder  | System                  | 11 Nov 2020 20:09:28 |
| Coding entries removed.  | Wendy Winn (b) (4)      | 11 Nov 2020 20:08:52 |
| User entered 'OSTEOARTHRITIS' reason for change: Data Entry Error  | (b) (4)                 |                      |
| Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid, Osteoarthritis, etc.) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.             | Wendy Winn (b) (4)      | 11 Nov 2020 20:08:52 |
| ' canceled (Site from DM).   | (b) (4), (b) (6)        | 06 Nov 2020 08:41:00 |
| User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid, Osteoarthritis, etc.) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. | (b) (4), (b) (6)        | 27 Oct 2020 18:20:52 |
| ' (Site from DM).  |                         |                      |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Arthritis - version MedDRA\23.0.  | Coder Import (b) (4)    | 09 Sep 2020 17:08:58 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.  | Coder Import (b) (4)    | 09 Sep 2020 17:08:58 |
| Data point term sent to Coder  | System                  | 09 Sep 2020 17:08:06 |
| User entered 'Arthritis'   | Cindy Trimmer (b) (4)   | 09 Sep 2020 17:07:23 |
|  | (b) (4)                 |                      |

US3422244

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:32

Start date (dd MMM yyyy)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded.  | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '30 Jun 1975' | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:07:23 |

US3422244

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:32

Start date completely unknown

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '0'          | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:07:23 |

US3422244

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:32

[Condition ongoing at study entry](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered 'Yes (Y)'    | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:07:23 |

US3422244

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:32

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

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered empty.       | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:07:23 |

US3422244

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:32

[Stop date completely unknown](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '0'          | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:07:23 |



US3422244

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:32

Start Month and Year (derived)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered 'Jun 1975' | System           | 09 Sep 2020 17:07:23 |

US3422244

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:32

Start Year (derived)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered '1975' | System           | 09 Sep 2020 17:07:23 |

US3422244

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:32

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered empty. | System           | 09 Sep 2020 17:07:23 |

US3422244

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:32

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered empty. | System           | 09 Sep 2020 17:07:23 |

US3422244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:32

[Were vital signs assessed?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered 'Yes (Y)'    | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:08:47 |

US3422244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:32

Date of assessment (*dd MMM yyyy*)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '9 Sep 2020' | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:08:47 |
|                           | (b) (4)                          |                      |

US3422244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:32

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

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '10:12'      | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:08:47 |

US3422244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:32

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

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered '9 Sep 2020 10:12' | System           | 09 Sep 2020 17:08:47 |



US3422244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:32

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

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '68' in      | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:08:47 |
| DataPoint set to visible. | (b) (4)<br>System                | 09 Sep 2020 15:51:57 |

US3422244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:32

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

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '132' lb     | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:08:47 |
| DataPoint set to visible. | (b) (4)<br>System                | 09 Sep 2020 15:51:57 |

US3422244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:32

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

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered '20.11250'   | System           | 09 Sep 2020 17:08:47 |
| DataPoint set to visible. | System           | 09 Sep 2020 15:51:57 |

US3422244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:32

[BMI units](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered 'kg/m2'      | System           | 09 Sep 2020 17:08:47 |
| DataPoint set to visible. | System           | 09 Sep 2020 15:51:57 |

US3422244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:32

Temperature (xxx.x)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded.  | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening if Visit 1 Day 1 and Screening occurred on the same day. Please update data fields accordingly.' (Site from DM).        | (b) (4)<br>(b) (4), (b) (6)      | 25 Sep 2020 18:22:14 |
| User entered missing code ND - Not Done; reason for change Data Entry Error  | Cindy Trimmer (b) (4)<br>(b) (4) | 25 Sep 2020 17:21:59 |
| Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening if Visit 1 Day 1 and Screening occurred on the same day. Please update data fields accordingly.' answered with 'ND' (Site from DM). | Cindy Trimmer (b) (4)<br>(b) (4) | 23 Sep 2020 18:56:58 |
| User closed query 'Data is required. Please provide.' (Site from System).  | (b) (4), (b) (6)                 | 23 Sep 2020 18:49:15 |
| User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening if Visit 1 Day 1 and Screening occurred on the same day. Please update data fields accordingly.' (Site from DM).        | (b) (4), (b) (6)                 | 23 Sep 2020 18:49:14 |
| Query 'Data is required. Please provide.' answered with 'ND' (Site from System).   | Cindy Trimmer (b) (4)<br>(b) (4) | 22 Sep 2020 15:38:33 |
| User opened query 'Data is required. Please provide.' (Site from System).  | System                           | 22 Sep 2020 15:38:26 |
| User entered empty; reason for change Data Entry Error   | Cindy Trimmer (b) (4)<br>(b) (4) | 22 Sep 2020 15:38:26 |
| User entered '98.9' F  | Cindy Trimmer (b) (4)<br>(b) (4) | 09 Sep 2020 17:08:47 |

US3422244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:32

[Route of measurement](#)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded.                              | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered empty; reason for change Data Entry Error | (b) (4)<br>Cindy Trimmer (b) (4) | 22 Sep 2020 15:38:26 |
| User entered 'Oral (Oral)'                             | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:08:47 |

US3422244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:32

[If Other, specify](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered empty.       | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:08:47 |

US3422244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:32

[Pulse \(xxx\)](#)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)        | 27 Apr 2021 22:08:20 |
| User signature succeeded.  | Clarence Creech (b) (4) | 05 Mar 2021 18:38:40 |
| User entered missing code ND - Not Done; reason for change Data Entry Error      | Cindy Trimmer (b) (4)   | 25 Sep 2020 17:21:59 |
| User closed query 'Data is required. Please provide.' (Site from System).        | (b) (4)                 |                      |
| Query 'Data is required. Please provide.' answered with 'ND' (Site from System). | (b) (4), (b) (6)        | 23 Sep 2020 18:49:17 |
| User opened query 'Data is required. Please provide.' (Site from System).        | System                  | 22 Sep 2020 15:38:26 |
| User entered empty; reason for change Data Entry Error                           | Cindy Trimmer (b) (4)   | 22 Sep 2020 15:38:26 |
| User entered '85'  | Cindy Trimmer (b) (4)   | 09 Sep 2020 17:08:47 |



US3422244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:32

[Pulse units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered 'bpm'  | System           | 25 Sep 2020 17:21:59 |
| User entered empty. | System           | 22 Sep 2020 15:38:26 |
| User entered 'bpm'  | System           | 09 Sep 2020 17:08:47 |

US3422244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)        | 27 Apr 2021 22:08:20 |
| User signature succeeded.  | Clarence Creech (b) (4) | 05 Mar 2021 18:38:40 |
| User entered missing code ND - Not Done; reason for change Data Entry Error      | Cindy Trimmer (b) (4)   | 25 Sep 2020 17:21:59 |
| User closed query 'Data is required. Please provide.' (Site from System).        | (b) (4)                 |                      |
| Query 'Data is required. Please provide.' answered with 'ND' (Site from System). | (b) (4), (b) (6)        | 23 Sep 2020 18:49:19 |
| User opened query 'Data is required. Please provide.' (Site from System).        | Cindy Trimmer (b) (4)   | 22 Sep 2020 15:38:40 |
| User entered empty; reason for change Data Entry Error                           | (b) (4)                 | 22 Sep 2020 15:38:26 |
| User entered '16'  | System                  | 22 Sep 2020 15:38:26 |
|  | Cindy Trimmer (b) (4)   | 22 Sep 2020 15:38:26 |
|  | (b) (4)                 |                      |
|  | Cindy Trimmer (b) (4)   | 09 Sep 2020 17:08:47 |
|  | (b) (4)                 |                      |

US3422244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:32

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered 'breaths/min' | System           | 25 Sep 2020 17:21:59 |
| User entered empty.        | System           | 22 Sep 2020 15:38:26 |
| User entered 'breaths/min' | System           | 09 Sep 2020 17:08:47 |

US3422244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:32

Systolic Blood Pressure (xxx)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)        | 27 Apr 2021 22:08:20 |
| User signature succeeded.  | Clarence Creech (b) (4) | 05 Mar 2021 18:38:40 |
| User entered missing code ND - Not Done; reason for change Data Entry Error      | Cindy Trimmer (b) (4)   | 25 Sep 2020 17:21:59 |
| User closed query 'Data is required. Please provide.' (Site from System).        | (b) (4)                 | 23 Sep 2020 18:49:21 |
| Query 'Data is required. Please provide.' answered with 'ND' (Site from System). | (b) (4), (b) (6)        | 22 Sep 2020 15:38:43 |
| User opened query 'Data is required. Please provide.' (Site from System).        | Cindy Trimmer (b) (4)   | 22 Sep 2020 15:38:26 |
| User entered empty; reason for change Data Entry Error                           | System                  | 22 Sep 2020 15:38:26 |
| User entered '127'   | Cindy Trimmer (b) (4)   | 22 Sep 2020 15:38:26 |
|  | (b) (4)                 | 09 Sep 2020 17:08:47 |

US3422244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:32

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered 'mmHg' | System           | 25 Sep 2020 17:21:59 |
| User entered empty. | System           | 22 Sep 2020 15:38:26 |
| User entered 'mmHg' | System           | 09 Sep 2020 17:08:47 |

US3422244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:32

Diastolic Blood Pressure (xxx)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)        | 27 Apr 2021 22:08:20 |
| User signature succeeded.  | Clarence Creech (b) (4) | 05 Mar 2021 18:38:40 |
| User entered missing code ND - Not Done; reason for change Data Entry Error      | Cindy Trimmer (b) (4)   | 25 Sep 2020 17:21:59 |
| User closed query 'Data is required. Please provide.' (Site from System).        | (b) (4)                 | 23 Sep 2020 18:49:23 |
| Query 'Data is required. Please provide.' answered with 'ND' (Site from System). | (b) (4), (b) (6)        | 22 Sep 2020 15:38:46 |
| User opened query 'Data is required. Please provide.' (Site from System).        | Cindy Trimmer (b) (4)   | 22 Sep 2020 15:38:26 |
| User entered empty; reason for change Data Entry Error                           | System                  | 22 Sep 2020 15:38:26 |
| User entered '74'  | Cindy Trimmer (b) (4)   | 22 Sep 2020 15:38:26 |
|  | (b) (4)                 | 09 Sep 2020 17:08:47 |
|  | (b) (4)                 |                      |

US3422244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:32

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered 'mmHg' | System           | 25 Sep 2020 17:21:59 |
| User entered empty. | System           | 22 Sep 2020 15:38:26 |
| User entered 'mmHg' | System           | 09 Sep 2020 17:08:47 |

US3422244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:32

[Height \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |



US3422244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:32

[Weight \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |

US3422244

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:32

[Was the physical examination performed?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered 'Yes (Y)'    | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:09:09 |

US3422244

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:32

Date of examination (dd MMM yyyy)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '9 Sep 2020' | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:09:09 |
|                           | (b) (4)                          |                      |

US3422244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:32

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 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered 'No (N)'     | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:10:57 |

US3422244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:32

[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 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered 'No (N)'     | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:10:57 |

US3422244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:32

**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 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered 'No (N)'     | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:10:57 |
|                           | (b) (4)                          |                      |

US3422244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:32

**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 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered 'No (N)'     | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:10:57 |
|                           | (b) (4)                          |                      |

US3422244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:32

[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 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered 'No (N)'     | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:10:57 |



US3422244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:32

[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 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered 'No (N)'     | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:10:57 |

US3422244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:32

**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 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered 'No (N)'     | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:10:57 |
|                           | (b) (4)                          |                      |

US3422244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:32

[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 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered 'No (N)'     | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:10:57 |
|                           | (b) (4)                          |                      |

US3422244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:32

[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 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered 'No (N)'     | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:10:57 |

US3422244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:32

**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 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered 'No (N)'     | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:10:57 |
|                           | (b) (4)                          |                      |

US3422244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:32

**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 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered 'No (N)'     | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:10:57 |
|                           | (b) (4)                          |                      |

US3422244

Folder: Screening

Form: Risk of Exposure

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[Other](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered 'Yes (Y)'    | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:10:57 |

US3422244

Folder: Screening

Form: Risk of Exposure

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[Specify](#)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded.   | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered 'Retired, volunteers for (b) (6)<br>(b) (6), very active outside the home' | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:10:57 |



US3422244

Folder: Screening

Form: Risk of Exposure

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No Risk Identified

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '0'          | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:10:57 |
|                           | (b) (4)                          |                      |

US3422244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:32

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

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4) | 05 Mar 2021 18:38:40 |
| User entered '0'          | Cindy Trimmer (b) (4)   | 09 Sep 2020 17:10:57 |

US3422244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:32

[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 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '0'          | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:10:57 |
|                           | (b) (4)                          |                      |

US3422244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:32

[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 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4) | 05 Mar 2021 18:38:40 |
| User entered '0'          | Cindy Trimmer (b) (4)   | 09 Sep 2020 17:10:57 |

US3422244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:32

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 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)                     | 05 Mar 2021 18:38:40 |
| User entered '0'          | (b) (4)<br>Cindy Trimmer (b) (4)<br>(b) (4) | 09 Sep 2020 17:10:57 |

US3422244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:32

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

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4) | 05 Mar 2021 18:38:40 |
| User entered '1'          | Cindy Trimmer (b) (4)   | 09 Sep 2020 17:10:57 |

US3422244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:32

[Other](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '0'          | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:10:57 |

US3422244

Folder: Screening

Form: Risk of Exposure

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[Specify](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered empty.       | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:10:57 |



US3422244

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:34:32

[Was this visit performed?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered 'Yes (Y)'    | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:11:12 |

US3422244

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:34:32

Visit date (dd MMM yyyy)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '9 Sep 2020' | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:11:12 |
|                           | (b) (4)                          |                      |

US3422244

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:34:32

[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 22:08:20 |
| User signature succeeded.      | Clarence Creech (b) (4)                     | 05 Mar 2021 18:38:40 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>Cindy Trimmer (b) (4)<br>(b) (4) | 09 Sep 2020 17:11:12 |

US3422244

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:34:32

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered 'VISIT1' | System           | 09 Sep 2020 17:11:12 |

US3422244

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:32

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

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 27 Apr 2021 22:08:20 |
| User signature succeeded.  | Clarence Creech (b) (4)                     | 05 Mar 2021 18:38:40 |
| User entered '09 SEP 2020' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 09 Sep 2020 15:29:23 |

US3422244

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:32

[What was the participant's randomization number?](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)                     | 05 Mar 2021 18:38:40 |
| User entered '190375'     | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 09 Sep 2020 15:29:23 |

US3422244

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:32

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

| Audit                         | User  | Time (GMT)           |
|-------------------------------|---|----------------------|
| Data hard locked.             | (b) (4), (b) (6)                            | 27 Apr 2021 22:08:20 |
| User signature succeeded.     | Clarence Creech (b) (4)                     | 05 Mar 2021 18:38:40 |
| User entered '>=65 years (3)' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 09 Sep 2020 15:29:23 |

US3422244

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:32

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:40 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 09 Sep 2020 15:53:15 |



US3422244

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:32

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:40 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 09 Sep 2020 15:53:15 |

US3422244

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:32

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:40 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 09 Sep 2020 15:53:15 |

US3422244

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:32

Diabetes (Type I, Type 2, or gestational)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:40 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 09 Sep 2020 15:53:15 |

US3422244

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:32

[Liver Disease](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:40 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 09 Sep 2020 15:53:15 |

US3422244

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.                            | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded.                    | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered 'No (N)'                        | (b) (4)<br>Cindy Trimmer (b) (4) | 22 Sep 2020 15:38:55 |
| Amendment Manager: DataPoint set to visible. | (b) (4)<br>System                | 19 Sep 2020 05:47:38 |
| Amendment Manager inserted this DataPoint.   | System                           | 19 Sep 2020 05:47:37 |

US3422244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:32

Height

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded.   | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User closed query 'CDM RQ: Please enter Not Done in the data field of the edc for Height and Weight. ' (Site from DM).  | (b) (4)<br>(b) (4), (b) (6)      | 25 Sep 2020 18:22:18 |
| Query 'CDM RQ: Please enter Not Done in the data field of the edc for Height and Weight. ' answered with 'corrected' (Site from DM).  | Cindy Trimmer (b) (4)<br>(b) (4) | 25 Sep 2020 17:22:20 |
| User entered missing code ND - Not Done; reason for change Data Entry Error   | Cindy Trimmer (b) (4)<br>(b) (4) | 25 Sep 2020 17:22:08 |
| User opened query 'CDM RQ: Please enter Not Done in the data field of the edc for Height and Weight. ' (Site from DM).  | (b) (4), (b) (6)                 | 24 Sep 2020 14:29:54 |
| User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).        | (b) (4), (b) (6)                 | 24 Sep 2020 14:29:54 |
| Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' answered with 'ND' (Site from DM). | Cindy Trimmer (b) (4)<br>(b) (4) | 23 Sep 2020 18:57:05 |
| User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).        | (b) (4), (b) (6)                 | 23 Sep 2020 18:49:40 |
| User entered empty; reason for change Data Entry Error  | Cindy Trimmer (b) (4)<br>(b) (4) | 22 Sep 2020 15:39:08 |
| User entered '68' in  | Cindy Trimmer (b) (4)<br>(b) (4) | 09 Sep 2020 17:12:12 |

US3422244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:32

[Weight](#)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded.   | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4)<br>Cindy Trimmer (b) (4) | 25 Sep 2020 17:22:08 |
| User entered empty; reason for change Data Entry Error                      | (b) (4)<br>Cindy Trimmer (b) (4) | 22 Sep 2020 15:39:08 |
| User entered '132' lb   | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:12:12 |

US3422244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:32

Height

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded.   | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:40 |
| User closed query 'CDM RQ: Please enter Not Done in the data field of the edc for Height and Weight. ' (Site from DM).  | (b) (4)<br>(b) (4), (b) (6) | 25 Sep 2020 18:22:18 |
| Query 'CDM RQ: Please enter Not Done in the data field of the edc for Height and Weight. ' answered with 'corrected' (Site from DM).  | Cindy Trimmer (b) (4)       | 25 Sep 2020 17:22:20 |
| User entered missing code ND - Not Done; reason for change Data Entry Error   | Cindy Trimmer (b) (4)       | 25 Sep 2020 17:22:08 |
| User opened query 'CDM RQ: Please enter Not Done in the data field of the edc for Height and Weight. ' (Site from DM).  | (b) (4), (b) (6)            | 24 Sep 2020 14:29:54 |
| User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).        | (b) (4), (b) (6)            | 24 Sep 2020 14:29:54 |
| Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' answered with 'ND' (Site from DM). | Cindy Trimmer (b) (4)       | 23 Sep 2020 18:57:05 |
| User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).        | (b) (4), (b) (6)            | 23 Sep 2020 18:49:40 |
| User entered empty; reason for change Data Entry Error  | Cindy Trimmer (b) (4)       | 22 Sep 2020 15:39:08 |
| User entered '68' in  | Cindy Trimmer (b) (4)       | 09 Sep 2020 17:12:12 |



US3422244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:32

[Weight](#)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded.   | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4)<br>Cindy Trimmer (b) (4) | 25 Sep 2020 17:22:08 |
| User entered empty; reason for change Data Entry Error                      | (b) (4)<br>Cindy Trimmer (b) (4) | 22 Sep 2020 15:39:08 |
| User entered '132' lb   | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:12:12 |

US3422244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:32

[Timepoint](#)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.                                | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Cindy Trimmer (b) (4)<br>(b) (4) | 09 Sep 2020 17:12:12 |

US3422244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:32

Were vital signs assessed?

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered 'Yes (Y)'    | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:12:12 |

US3422244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:32

Date of assessment (*dd MMM yyyy*)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '9 Sep 2020' | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:12:12 |
|                           | (b) (4)                          |                      |

US3422244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:32

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

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '10:12'      | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:12:12 |

US3422244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:32

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

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered '9 Sep 2020 10:12' | System           | 09 Sep 2020 17:12:12 |

US3422244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:32

Temperature (xxx.x)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '98.9' F     | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:12:12 |
|                           | (b) (4)                          |                      |

US3422244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:32

[Route of measurement](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded.  | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered 'Oral (Oral)' | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:12:12 |
|                            | (b) (4)                          |                      |



US3422244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:32

[If Other, specify](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered empty.       | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:12:12 |
|                           | (b) (4)                          |                      |

US3422244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:32

[Pulse \(xxx\)](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '85'         | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:12:12 |

US3422244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:32

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered 'bpm' | System           | 09 Sep 2020 17:12:12 |

US3422244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:32

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

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '16'         | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:12:12 |

US3422244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:32

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered 'breaths/min' | System           | 09 Sep 2020 17:12:12 |

US3422244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:32

Systolic Blood Pressure (xxx)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '127'        | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:12:12 |

US3422244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:32

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered 'mmHg' | System           | 09 Sep 2020 17:12:12 |

US3422244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:32

Diastolic Blood Pressure (xxx)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '74'         | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:12:12 |



US3422244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:32

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered 'mmHg' | System           | 09 Sep 2020 17:12:12 |

US3422244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:32

Height

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded.   | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User closed query 'CDM RQ: Please enter Not Done in the data field of the edc for Height and Weight. ' (Site from DM).  | (b) (4)<br>(b) (4), (b) (6)      | 25 Sep 2020 18:22:18 |
| Query 'CDM RQ: Please enter Not Done in the data field of the edc for Height and Weight. ' answered with 'corrected' (Site from DM).  | Cindy Trimmer (b) (4)<br>(b) (4) | 25 Sep 2020 17:22:20 |
| User entered missing code ND - Not Done; reason for change Data Entry Error   | Cindy Trimmer (b) (4)<br>(b) (4) | 25 Sep 2020 17:22:08 |
| User opened query 'CDM RQ: Please enter Not Done in the data field of the edc for Height and Weight. ' (Site from DM).  | (b) (4), (b) (6)                 | 24 Sep 2020 14:29:54 |
| User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).        | (b) (4), (b) (6)                 | 24 Sep 2020 14:29:54 |
| Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' answered with 'ND' (Site from DM). | Cindy Trimmer (b) (4)<br>(b) (4) | 23 Sep 2020 18:57:05 |
| User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).        | (b) (4), (b) (6)                 | 23 Sep 2020 18:49:40 |
| User entered empty; reason for change Data Entry Error  | Cindy Trimmer (b) (4)<br>(b) (4) | 22 Sep 2020 15:39:08 |
| User entered '68' in  | Cindy Trimmer (b) (4)<br>(b) (4) | 09 Sep 2020 17:12:12 |

US3422244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:32

[Weight](#)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded.   | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4)<br>Cindy Trimmer (b) (4) | 25 Sep 2020 17:22:08 |
| User entered empty; reason for change Data Entry Error                      | (b) (4)<br>Cindy Trimmer (b) (4) | 22 Sep 2020 15:39:08 |
| User entered '132' lb   | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:12:12 |

US3422244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:32

[Timepoint](#)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Cindy Trimmer (b) (4)<br>(b) (4) | 09 Sep 2020 17:12:12 |

US3422244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:32

Were vital signs assessed?

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered 'Yes (Y)'    | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:12:12 |

US3422244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:32

Date of assessment (*dd MMM yyyy*)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '9 Sep 2020' | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:12:12 |

US3422244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:32

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

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '11:12'      | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:12:12 |

US3422244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:32

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

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered '9 Sep 2020 11:12' | System           | 09 Sep 2020 17:12:12 |



US3422244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:32

Temperature (xxx.x)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '98.3' F     | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:12:12 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:32

[Route of measurement](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded.  | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered 'Oral (Oral)' | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:12:12 |
|                            | (b) (4)                          |                      |

US3422244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:32

[If Other, specify](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered empty.       | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:12:12 |
|                           | (b) (4)                          |                      |

US3422244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:32

[Pulse \(xxx\)](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '81'         | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:12:12 |

US3422244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:32

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered 'bpm' | System           | 09 Sep 2020 17:12:12 |

US3422244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:32

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

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '16'         | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:12:12 |

US3422244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:32

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered 'breaths/min' | System           | 09 Sep 2020 17:12:12 |

US3422244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:32

Systolic Blood Pressure (xxx)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '140'        | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:12:12 |



US3422244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:32

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered 'mmHg' | System           | 09 Sep 2020 17:12:12 |

US3422244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:32

Diastolic Blood Pressure (xxx)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '85'         | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:12:12 |
|                           | (b) (4)                          |                      |

US3422244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:32

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered 'mmHg' | System           | 09 Sep 2020 17:12:12 |

US3422244

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:32

[Was the physical examination performed?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered 'No (N)'     | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:12:19 |

US3422244

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:32

Date of examination (dd MMM yyyy)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered empty.       | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:12:19 |

US3422244

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:32

[Was study treatment given?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:40 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 09 Sep 2020 15:52:25 |

US3422244

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:32

[If No, reason not given](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:40 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 09 Sep 2020 15:52:25 |

US3422244

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:32

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:40 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 09 Sep 2020 15:52:25 |



US3422244

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:32

[What was the study treatment?](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| Data hard locked.                   | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered 'MRNA-1273 OR PLACEBO' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:32

What was the treatment date? (dd MMM yyyy)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:40 |
| User entered '9 Sep 2020' | (b) (4)<br>(b) (4), (b) (6) | 09 Sep 2020 15:52:25 |

US3422244

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:32

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:40 |
| User entered '10:48'      | (b) (4)<br>(b) (4), (b) (6) | 09 Sep 2020 15:52:25 |

US3422244

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:32

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

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered '9 Sep 2020 10:48' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:32

Which arm was used to give treatment?

| Audit                              | User                        | Time (GMT)           |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded.          | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:40 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4)<br>(b) (4), (b) (6) | 09 Sep 2020 15:52:25 |

US3422244

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:32

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered 'ONCE' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:32

What was the route of administration for the study treatment?

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered 'INTRAMUSCULAR' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:32

[Was the sample collected?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered 'Yes (Y)'    | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:12:41 |



US3422244

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:32

Collection date (dd MMM yyyy)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '9 Sep 2020' | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:12:41 |

US3422244

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:32

Collection time (00:00-23:59)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '10:25'      | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:12:41 |

US3422244

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:32

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

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered '9 Sep 2020 10:25' | System           | 09 Sep 2020 17:12:41 |

US3422244

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:34:32

Collection date (*dd MMM yyyy*)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '9 Sep 2020' | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:12:54 |
|                           | (b) (4)                          |                      |

US3422244

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:34:32

[Lab Test](#)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Cindy Trimmer (b) (4)<br>(b) (4) | 09 Sep 2020 17:12:54 |

US3422244

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:34:32

[Was the sample collected?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered 'Yes (Y)'    | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:12:54 |

US3422244

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:34:32

Collection time (00:00 - 23:59)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4) | 05 Mar 2021 18:38:40 |
| User entered '10:16'      | Cindy Trimmer (b) (4)   | 09 Sep 2020 17:12:54 |

US3422244

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:34:32

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

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered '9 Sep 2020 10:16' | System           | 09 Sep 2020 17:12:54 |



US3422244

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:34:32

[Lab Test](#)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Cindy Trimmer (b) (4)<br>(b) (4) | 09 Sep 2020 17:12:54 |

US3422244

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:34:32

[Was the sample collected?](#)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)        | 27 Apr 2021 22:08:20 |
| User signature succeeded.  | Clarence Creech (b) (4) | 05 Mar 2021 18:38:40 |
| User closed query 'Data is required. Please complete.' (Site from System).             | (b) (4)                 | 09 Sep 2020 17:12:57 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                  | 09 Sep 2020 17:12:57 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Cindy Trimmer (b) (4)   | 09 Sep 2020 17:12:57 |
| User opened query 'Data is required. Please complete.' (Site from System).             | (b) (4)                 | 09 Sep 2020 17:12:54 |
| User entered empty.  | System                  | 09 Sep 2020 17:12:54 |
|  | Cindy Trimmer (b) (4)   | 09 Sep 2020 17:12:54 |
|  | (b) (4)                 |                      |

US3422244

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:34:32

Collection time (00:00 - 23:59)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)                     | 05 Mar 2021 18:38:40 |
| User entered empty.       | (b) (4)<br>Cindy Trimmer (b) (4)<br>(b) (4) | 09 Sep 2020 17:12:54 |

US3422244

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:34:32

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered empty. | System           | 09 Sep 2020 17:12:54 |

US3422244

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:34:32

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

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered 'Yes (Y)'    | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:13:01 |

US3422244

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:34:32

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered '1'  | System           | 09 Sep 2020 17:13:01 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.   | System           | 09 Sep 2020 15:52:25 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-09T11:12:27', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'fc769e3c-c3dd-4a36-8e48-78e028188de1' User entered 'Yes (Y)' | System           | 09 Sep 2020 16:13:01 |
|   | System           | 09 Sep 2020 16:13:01 |



US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-09T11:12:35', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'fc769e3c-c3dd-4a36-8e48-78e028188de1' User entered '98.3' | System           | 09 Sep 2020 16:13:01 |
|  | System           | 09 Sep 2020 16:13:01 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-09T11:12:42', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'fc769e3c-c3dd-4a36-8e48-78e028188de1' User entered 'No (N)' | System           | 09 Sep 2020 16:13:01 |
|  | System           | 09 Sep 2020 16:13:01 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-09T11:12:59', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'fc769e3c-c3dd-4a36-8e48-78e028188de1' User entered '09 Sep 2020 11:12' | System           | 09 Sep 2020 16:13:01 |
|   | System           | 09 Sep 2020 16:13:01 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '09 Sep 2020 11:08' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '09 Sep 2020 13:38' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.                                | System           | 09 Sep 2020 15:52:25 |
| User entered 'Day 1, after vaccination (at home)' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-09T19:40:04', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '55bf8310-d258-4d50-98e8-5b4125bb6459' | System           | 10 Sep 2020 00:40:35 |
| User entered 'Yes (Y)'   | System           | 10 Sep 2020 00:40:35 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-09T19:40:15', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '55bf8310-d258-4d50-98e8-5b4125bb6459' | System           | 10 Sep 2020 00:40:35 |
| User entered '98.6'  | System           | 10 Sep 2020 00:40:35 |



US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-09T19:40:21', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '55bf8310-d258-4d50-98e8-5b4125bb6459' | System           | 10 Sep 2020 00:40:35 |
| User entered 'No (N)'  | System           | 10 Sep 2020 00:40:35 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-09T19:40:29', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '55bf8310-d258-4d50-98e8-5b4125bb6459' User entered '09 Sep 2020 19:40' | System           | 10 Sep 2020 00:40:35 |
|   | System           | 10 Sep 2020 00:40:35 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '09 Sep 2020 14:33' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '10 Sep 2020 11:59' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.   | System           | 09 Sep 2020 15:52:25 |
| User entered 'Day 2' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:32

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-11T07:24:40', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'e5326fc6-c454-47c6-bd01-ae50563dfa21' | System           | 11 Sep 2020 12:25:09 |
| User entered 'Yes (Y)'   | System           | 11 Sep 2020 12:25:09 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:32

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-11T07:24:49', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'e5326fc6-c454-47c6-bd01-ae50563dfa21' User entered '97.8' | System           | 11 Sep 2020 12:25:09 |
|  | System           | 11 Sep 2020 12:25:09 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-11T07:24:55', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'e5326fc6-c454-47c6-bd01-ae50563dfa21' | System           | 11 Sep 2020 12:25:09 |
| User entered 'No (N)'  | System           | 11 Sep 2020 12:25:09 |



US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:32

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-11T07:25:06', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'e5326fc6-c454-47c6-bd01-ae50563dfa21' | System           | 11 Sep 2020 12:25:09 |
| User entered '11 Sep 2020 07:25'   | System           | 11 Sep 2020 12:25:09 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '10 Sep 2020 12:00' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '11 Sep 2020 11:59' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.   | System           | 09 Sep 2020 15:52:25 |
| User entered 'Day 3' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:32

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-11T21:25:58', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '21e5749c-fb61-4eed-bbb3-f22e8b7b6949' User entered 'Yes (Y)' | System           | 12 Sep 2020 02:27:35 |
|   | System           | 12 Sep 2020 02:27:35 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:32

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-11T21:26:08', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '21e5749c-fb61-4eed-bbb3-f22e8b7b6949' User entered '98.3' | System           | 12 Sep 2020 02:27:35 |
|  | System           | 12 Sep 2020 02:27:35 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-11T21:26:13', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '21e5749c-fb61-4eed-bbb3-f22e8b7b6949' | System           | 12 Sep 2020 02:27:35 |
| User entered 'No (N)'  | System           | 12 Sep 2020 02:27:35 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:32

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-11T21:26:20', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '21e5749c-fb61-4eed-bbb3-f22e8b7b6949' User entered '11 Sep 2020 21:26' | System           | 12 Sep 2020 02:27:35 |
|   | System           | 12 Sep 2020 02:27:35 |



US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '11 Sep 2020 12:00' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '12 Sep 2020 11:59' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.   | System           | 09 Sep 2020 15:52:25 |
| User entered 'Day 4' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:32

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-13T10:38:13', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'abb1b8a-5968-4504-b3d2-41301e1b56b6' User entered 'Yes (Y)' | System           | 13 Sep 2020 15:38:36 |
|  | System           | 13 Sep 2020 15:38:36 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:32

Please record your **TEMPERATURE** in °F

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-13T10:38:23', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'abb1b8a-5968-4504-b3d2-41301e1b56b6' User entered '97.9' | System           | 13 Sep 2020 15:38:36 |
|   | System           | 13 Sep 2020 15:38:36 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:32

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

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-13T10:38:28', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'abb1b8a-5968-4504-b3d2-41301e1b56b6' | System           | 13 Sep 2020 15:38:36 |
| User entered 'No (N)'   | System           | 13 Sep 2020 15:38:36 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:32

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-13T10:38:32', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'abb1b8a-5968-4504-b3d2-41301e1b56b6' User entered '13 Sep 2020 10:38' | System           | 13 Sep 2020 15:38:36 |
|  | System           | 13 Sep 2020 15:38:36 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '12 Sep 2020 12:00' | System           | 09 Sep 2020 15:52:25 |



US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '13 Sep 2020 11:59' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.   | System           | 09 Sep 2020 15:52:25 |
| User entered 'Day 5' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:32

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-13T21:35:29', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'ac3f88d1-ddb8-469b-aaae-bb6b9d49d409' | System           | 14 Sep 2020 02:35:54 |
| User entered 'Yes (Y)'   | System           | 14 Sep 2020 02:35:54 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:32

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-13T21:35:41', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'ac3f88d1-ddb8-469b-aaae-bb6b9d49d409' User entered '98.2' | System           | 14 Sep 2020 02:35:54 |
|  | System           | 14 Sep 2020 02:35:54 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-13T21:35:45', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'ac3f88d1-ddb8-469b-aaae-bb6b9d49d409' | System           | 14 Sep 2020 02:35:54 |
| User entered 'No (N)'  | System           | 14 Sep 2020 02:35:54 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:32

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-13T21:35:50', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'ac3f88d1-ddb8-469b-aaae-bb6b9d49d409' User entered '13 Sep 2020 21:35' | System           | 14 Sep 2020 02:35:54 |
|   | System           | 14 Sep 2020 02:35:54 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '13 Sep 2020 12:00' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '14 Sep 2020 11:59' | System           | 09 Sep 2020 15:52:25 |



US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.   | System           | 09 Sep 2020 15:52:25 |
| User entered 'Day 6' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:32

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-14T12:34:46', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '8fd95164-e312-44bd-bb54-dce2b6fea096' | System           | 14 Sep 2020 17:35:09 |
| User entered 'Yes (Y)'   | System           | 14 Sep 2020 17:35:09 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:32

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-14T12:34:58', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '8fd95164-e312-44bd-bb54-dce2b6fea096' User entered '98.5' | System           | 14 Sep 2020 17:35:09 |
|  | System           | 14 Sep 2020 17:35:09 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-14T12:35:02', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '8fd95164-e312-44bd-bb54-dce2b6fea096' | System           | 14 Sep 2020 17:35:09 |
| User entered 'No (N)'  | System           | 14 Sep 2020 17:35:09 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:32

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-14T12:35:06', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '8fd95164-e312-44bd-bb54-dce2b6fea096' | System           | 14 Sep 2020 17:35:09 |
| User entered '14 Sep 2020 12:35'   | System           | 14 Sep 2020 17:35:09 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '14 Sep 2020 12:00' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '15 Sep 2020 11:59' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.   | System           | 09 Sep 2020 15:52:25 |
| User entered 'Day 7' | System           | 09 Sep 2020 15:52:25 |



US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:32

Was **TEMPERATURE** taken?

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:32

Please record your **TEMPERATURE** in °F

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:32

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:32

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:32

To **PREVENT** pain or fever from occurring

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:32

[PC Time Stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '15 Sep 2020 12:00' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '16 Sep 2020 11:59' | System           | 09 Sep 2020 15:52:25 |



US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.   | System           | 09 Sep 2020 15:52:25 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-09T11:13:46', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '79f5a7ae-99da-41f0-825b-96d265938195' | System           | 09 Sep 2020 16:14:13 |
| User entered 'None (1)'  | System           | 09 Sep 2020 16:14:13 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-09T11:13:53', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '79f5a7ae-99da-41f0-825b-96d265938195' | System           | 09 Sep 2020 16:14:13 |
| User entered 'No (N)'  | System           | 09 Sep 2020 16:14:13 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-09T11:13:58', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '79f5a7ae-99da-41f0-825b-96d265938195' | System           | 09 Sep 2020 16:14:13 |
| User entered 'No (N)'  | System           | 09 Sep 2020 16:14:13 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-09T11:14:02', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '79f5a7ae-99da-41f0-825b-96d265938195' | System           | 09 Sep 2020 16:14:13 |
| User entered 'None (1)'  | System           | 09 Sep 2020 16:14:13 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-09T11:14:11', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '79f5a7ae-99da-41f0-825b-96d265938195' User entered '09 Sep 2020 11:14' | System           | 09 Sep 2020 16:14:13 |
|   | System           | 09 Sep 2020 16:14:13 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '09 Sep 2020 11:08' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '09 Sep 2020 13:38' | System           | 09 Sep 2020 15:52:25 |



US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.                                | System           | 09 Sep 2020 15:52:25 |
| User entered 'Day 1, after vaccination (at home)' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-09T19:41:54', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'd9781acd-6dc5-4ed9-8c9b-08fc75935952' | System           | 10 Sep 2020 00:42:16 |
| User entered 'None (1)'  | System           | 10 Sep 2020 00:42:16 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-09T19:41:58', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'd9781acd-6dc5-4ed9-8c9b-08fc75935952' | System           | 10 Sep 2020 00:42:16 |
| User entered 'No (N)'  | System           | 10 Sep 2020 00:42:16 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-09T19:42:03', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'd9781acd-6dc5-4ed9-8c9b-08fc75935952' | System           | 10 Sep 2020 00:42:16 |
| User entered 'No (N)'  | System           | 10 Sep 2020 00:42:16 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-09T19:42:09', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'd9781acd-6dc5-4ed9-8c9b-08fc75935952' | System           | 10 Sep 2020 00:42:16 |
| User entered 'None (1)'  | System           | 10 Sep 2020 00:42:16 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-09T19:42:12', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'd9781acd-6dc5-4ed9-8c9b-08fc75935952' User entered '09 Sep 2020 19:42' | System           | 10 Sep 2020 00:42:16 |
|   | System           | 10 Sep 2020 00:42:16 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '09 Sep 2020 14:33' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '10 Sep 2020 11:59' | System           | 09 Sep 2020 15:52:25 |



US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.   | System           | 09 Sep 2020 15:52:25 |
| User entered 'Day 2' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:32

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-11T07:26:11', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'e4ce06f2-ffd7-4ab6-92d0-d2e890b95546' | System           | 11 Sep 2020 12:26:46 |
| User entered 'None (1)'  | System           | 11 Sep 2020 12:26:46 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-11T07:26:22', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'e4ce06f2-ffd7-4ab6-92d0-d2e890b95546' | System           | 11 Sep 2020 12:26:46 |
| User entered 'No (N)'  | System           | 11 Sep 2020 12:26:46 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-11T07:26:29', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'e4ce06f2-ffd7-4ab6-92d0-d2e890b95546' | System           | 11 Sep 2020 12:26:46 |
| User entered 'No (N)'  | System           | 11 Sep 2020 12:26:46 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:32

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-11T07:26:39', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'e4ce06f2-ffd7-4ab6-92d0-d2e890b95546' | System           | 11 Sep 2020 12:26:46 |
| User entered 'None (1)'  | System           | 11 Sep 2020 12:26:46 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:32

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-11T07:26:42', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'e4ce06f2-ffd7-4ab6-92d0-d2e890b95546' | System           | 11 Sep 2020 12:26:46 |
| User entered '11 Sep 2020 07:26'   | System           | 11 Sep 2020 12:26:46 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '10 Sep 2020 12:00' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '11 Sep 2020 11:59' | System           | 09 Sep 2020 15:52:25 |



US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.   | System           | 09 Sep 2020 15:52:25 |
| User entered 'Day 3' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:32

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-11T21:26:30', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '0ac21827-c478-4052-a02d-2c1718da5ee0' User entered 'None (1)' | System           | 12 Sep 2020 02:27:47 |
|  | System           | 12 Sep 2020 02:27:47 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-11T21:26:35', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '0ac21827-c478-4052-a02d-2c1718da5ee0' User entered 'No (N)' | System           | 12 Sep 2020 02:27:47 |
|  | System           | 12 Sep 2020 02:27:47 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-11T21:26:39', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '0ac21827-c478-4052-a02d-2c1718da5ee0' User entered 'No (N)' | System           | 12 Sep 2020 02:27:47 |
|  | System           | 12 Sep 2020 02:27:47 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:32

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-11T21:26:44', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '0ac21827-c478-4052-a02d-2c1718da5ee0' User entered 'None (1)' | System           | 12 Sep 2020 02:27:47 |
|  | System           | 12 Sep 2020 02:27:47 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:32

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-11T21:26:48', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '0ac21827-c478-4052-a02d-2c1718da5ee0' User entered '11 Sep 2020 21:26' | System           | 12 Sep 2020 02:27:47 |
|   | System           | 12 Sep 2020 02:27:47 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '11 Sep 2020 12:00' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '12 Sep 2020 11:59' | System           | 09 Sep 2020 15:52:25 |



US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.   | System           | 09 Sep 2020 15:52:25 |
| User entered 'Day 4' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:32

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-13T10:38:37', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '3afe317d-fa4f-4365-b521-7a9d9a849ed9' User entered 'None (1)' | System           | 13 Sep 2020 15:39:04 |
|  | System           | 13 Sep 2020 15:39:04 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-13T10:38:44', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '3afe317d-fa4f-4365-b521-7a9d9a849ed9' | System           | 13 Sep 2020 15:39:04 |
| User entered 'No (N)'  | System           | 13 Sep 2020 15:39:04 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-13T10:38:49', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '3afe317d-fa4f-4365-b521-7a9d9a849ed9' | System           | 13 Sep 2020 15:39:04 |
| User entered 'No (N)'  | System           | 13 Sep 2020 15:39:04 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:32

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-13T10:38:52', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '3afe317d-fa4f-4365-b521-7a9d9a849ed9' | System           | 13 Sep 2020 15:39:04 |
| User entered 'None (1)'  | System           | 13 Sep 2020 15:39:04 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:32

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-13T10:38:55', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '3afe317d-fa4f-4365-b521-7a9d9a849ed9' User entered '13 Sep 2020 10:38' | System           | 13 Sep 2020 15:39:04 |
|   | System           | 13 Sep 2020 15:39:04 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '12 Sep 2020 12:00' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '13 Sep 2020 11:59' | System           | 09 Sep 2020 15:52:25 |



US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.   | System           | 09 Sep 2020 15:52:25 |
| User entered 'Day 5' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:32

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-13T21:35:56', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '5d267770-3f0b-4401-ba53-d7315e4754a2' | System           | 14 Sep 2020 02:36:12 |
| User entered 'None (1)'  | System           | 14 Sep 2020 02:36:12 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-13T21:35:59', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '5d267770-3f0b-4401-ba53-d7315e4754a2' | System           | 14 Sep 2020 02:36:12 |
| User entered 'No (N)'  | System           | 14 Sep 2020 02:36:12 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-13T21:36:04', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '5d267770-3f0b-4401-ba53-d7315e4754a2' | System           | 14 Sep 2020 02:36:12 |
| User entered 'No (N)'  | System           | 14 Sep 2020 02:36:12 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:32

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-13T21:36:07', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '5d267770-3f0b-4401-ba53-d7315e4754a2' | System           | 14 Sep 2020 02:36:12 |
| User entered 'None (1)'  | System           | 14 Sep 2020 02:36:12 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:32

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-13T21:36:11', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '5d267770-3f0b-4401-ba53-d7315e4754a2' | System           | 14 Sep 2020 02:36:12 |
| User entered '13 Sep 2020 21:36'   | System           | 14 Sep 2020 02:36:12 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '13 Sep 2020 12:00' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '14 Sep 2020 11:59' | System           | 09 Sep 2020 15:52:25 |



US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.   | System           | 09 Sep 2020 15:52:25 |
| User entered 'Day 6' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:32

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-14T12:35:14', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '3c42dbb0-a770-4dc1-8e0f-72d079b3b190' User entered 'None (1)' | System           | 14 Sep 2020 17:35:29 |
|  | System           | 14 Sep 2020 17:35:29 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-14T12:35:17', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '3c42dbb0-a770-4dc1-8e0f-72d079b3b190' | System           | 14 Sep 2020 17:35:29 |
| User entered 'No (N)'  | System           | 14 Sep 2020 17:35:29 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-14T12:35:20', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '3c42dbb0-a770-4dc1-8e0f-72d079b3b190' User entered 'No (N)' | System           | 14 Sep 2020 17:35:29 |
|  | System           | 14 Sep 2020 17:35:29 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:32

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-14T12:35:23', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '3c42dbb0-a770-4dc1-8e0f-72d079b3b190' User entered 'None (1)' | System           | 14 Sep 2020 17:35:29 |
|  | System           | 14 Sep 2020 17:35:29 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:32

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-14T12:35:27', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '3c42dbb0-a770-4dc1-8e0f-72d079b3b190' User entered '14 Sep 2020 12:35' | System           | 14 Sep 2020 17:35:29 |
|   | System           | 14 Sep 2020 17:35:29 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '14 Sep 2020 12:00' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '15 Sep 2020 11:59' | System           | 09 Sep 2020 15:52:25 |



US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.   | System           | 09 Sep 2020 15:52:25 |
| User entered 'Day 7' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:32

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

Please select one response below

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:32

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:32

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

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:32

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:32

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

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:32

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

Please select one response below

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:32

[PC Time Stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |



US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '15 Sep 2020 12:00' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '16 Sep 2020 11:59' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.   | System           | 09 Sep 2020 15:52:25 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-09T11:14:29', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '42bee3ca-8808-481c-89e5-1bae9ff022e4' User entered 'None (0)' | System           | 09 Sep 2020 16:14:58 |
|  | System           | 09 Sep 2020 16:14:58 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-09T11:14:34', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '42bee3ca-8808-481c-89e5-1bae9ff022e4' User entered 'None (0)' | System           | 09 Sep 2020 16:14:58 |
|  | System           | 09 Sep 2020 16:14:58 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-09T11:14:36', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '42bee3ca-8808-481c-89e5-1bae9ff022e4' User entered 'None (0)' | System           | 09 Sep 2020 16:14:58 |
|  | System           | 09 Sep 2020 16:14:58 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-09T11:14:39', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '42bee3ca-8808-481c-89e5-1bae9ff022e4' User entered 'None (0)' | System           | 09 Sep 2020 16:14:58 |
|  | System           | 09 Sep 2020 16:14:58 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-09T11:14:43', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '42bee3ca-8808-481c-89e5-1bae9ff022e4' User entered 'None (0)' | System           | 09 Sep 2020 16:14:58 |
|  | System           | 09 Sep 2020 16:14:58 |



US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-09T11:14:46', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '42bee3ca-8808-481c-89e5-1bae9ff022e4' User entered 'None (0)' | System           | 09 Sep 2020 16:14:58 |
|  | System           | 09 Sep 2020 16:14:58 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

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) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-09T11:14:52', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '42bee3ca-8808-481c-89e5-1bae9ff022e4' User entered 'No (N)' | System           | 09 Sep 2020 16:14:58 |
|  | System           | 09 Sep 2020 16:14:58 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-09T11:14:56', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '42bee3ca-8808-481c-89e5-1bae9ff022e4' User entered '09 Sep 2020 11:14' | System           | 09 Sep 2020 16:14:58 |
|   | System           | 09 Sep 2020 16:14:58 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '09 Sep 2020 11:08' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '09 Sep 2020 13:38' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.                                | System           | 09 Sep 2020 15:52:25 |
| User entered 'Day 1, after vaccination (at home)' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-09T19:41:12', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '1c1f7a24-31c8-4a6d-a046-4fad7a995e4a' User entered 'None (0)' | System           | 10 Sep 2020 00:41:44 |
|  | System           | 10 Sep 2020 00:41:44 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-09T19:41:16', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '1c1f7a24-31c8-4a6d-a046-4fad7a995e4a' User entered 'None (0)' | System           | 10 Sep 2020 00:41:44 |
|  | System           | 10 Sep 2020 00:41:44 |



US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-09T19:41:19', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '1c1f7a24-31c8-4a6d-a046-4fad7a995e4a' User entered 'None (0)' | System           | 10 Sep 2020 00:41:44 |
|  | System           | 10 Sep 2020 00:41:44 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-09T19:41:23', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '1c1f7a24-31c8-4a6d-a046-4fad7a995e4a' User entered 'None (0)' | System           | 10 Sep 2020 00:41:44 |
|  | System           | 10 Sep 2020 00:41:44 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-09T19:41:26', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '1c1f7a24-31c8-4a6d-a046-4fad7a995e4a' User entered 'None (0)' | System           | 10 Sep 2020 00:41:44 |
|  | System           | 10 Sep 2020 00:41:44 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-09T19:41:28', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '1c1f7a24-31c8-4a6d-a046-4fad7a995e4a' User entered 'None (0)' | System           | 10 Sep 2020 00:41:44 |
|  | System           | 10 Sep 2020 00:41:44 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

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) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-09T19:41:35', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '1c1f7a24-31c8-4a6d-a046-4fad7a995e4a' | System           | 10 Sep 2020 00:41:44 |
| User entered 'No (N)'  | System           | 10 Sep 2020 00:41:44 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-09T19:41:41', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '1c1f7a24-31c8-4a6d-a046-4fad7a995e4a' User entered '09 Sep 2020 19:41' | System           | 10 Sep 2020 00:41:44 |
|   | System           | 10 Sep 2020 00:41:44 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '09 Sep 2020 14:33' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '10 Sep 2020 11:59' | System           | 09 Sep 2020 15:52:25 |



US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.   | System           | 09 Sep 2020 15:52:25 |
| User entered 'Day 2' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:32

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-11T07:25:25', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'f2e28a5e-a79a-49da-8307-ba6775a6d5e0' User entered 'None (0)' | System           | 11 Sep 2020 12:25:59 |
|  | System           | 11 Sep 2020 12:25:59 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:32

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-11T07:25:30', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'f2e28a5e-a79a-49da-8307-ba6775a6d5e0' User entered 'None (0)' | System           | 11 Sep 2020 12:25:59 |
|  | System           | 11 Sep 2020 12:25:59 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:32

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-11T07:25:33', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'f2e28a5e-a79a-49da-8307-ba6775a6d5e0' User entered 'None (0)' | System           | 11 Sep 2020 12:25:59 |
|  | System           | 11 Sep 2020 12:25:59 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:32

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-11T07:25:37', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'f2e28a5e-a79a-49da-8307-ba6775a6d5e0' User entered 'None (0)' | System           | 11 Sep 2020 12:25:59 |
|  | System           | 11 Sep 2020 12:25:59 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:32

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-11T07:25:40', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'f2e28a5e-a79a-49da-8307-ba6775a6d5e0' User entered 'None (0)' | System           | 11 Sep 2020 12:25:59 |
|  | System           | 11 Sep 2020 12:25:59 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:32

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-11T07:25:43', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'f2e28a5e-a79a-49da-8307-ba6775a6d5e0' User entered 'None (0)' | System           | 11 Sep 2020 12:25:59 |
|  | System           | 11 Sep 2020 12:25:59 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:32

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) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-11T07:25:52', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'f2e28a5e-a79a-49da-8307-ba6775a6d5e0' User entered 'No (N)' | System           | 11 Sep 2020 12:25:59 |
|  | System           | 11 Sep 2020 12:25:59 |



US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:32

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-11T07:25:56', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'f2e28a5e-a79a-49da-8307-ba6775a6d5e0' User entered '11 Sep 2020 07:25' | System           | 11 Sep 2020 12:25:59 |
|   | System           | 11 Sep 2020 12:25:59 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '10 Sep 2020 12:00' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '11 Sep 2020 11:59' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.   | System           | 09 Sep 2020 15:52:25 |
| User entered 'Day 3' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:32

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-11T21:26:59', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '532424bb-4aa4-404c-8454-5a64d81c8da0' User entered 'None (0)' | System           | 12 Sep 2020 02:28:01 |
|  | System           | 12 Sep 2020 02:28:01 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:32

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-11T21:27:02', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '532424bb-4aa4-404c-8454-5a64d81c8da0' | System           | 12 Sep 2020 02:28:01 |
| User entered 'None (0)'  | System           | 12 Sep 2020 02:28:01 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:32

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-11T21:27:06', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '532424bb-4aa4-404c-8454-5a64d81c8da0' User entered 'None (0)' | System           | 12 Sep 2020 02:28:01 |
|  | System           | 12 Sep 2020 02:28:01 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:32

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-11T21:27:09', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '532424bb-4aa4-404c-8454-5a64d81c8da0' User entered 'None (0)' | System           | 12 Sep 2020 02:28:01 |
|  | System           | 12 Sep 2020 02:28:01 |



US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:32

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-11T21:27:12', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '532424bb-4aa4-404c-8454-5a64d81c8da0' User entered 'None (0)' | System           | 12 Sep 2020 02:28:01 |
|  | System           | 12 Sep 2020 02:28:01 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:32

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-11T21:27:16', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '532424bb-4aa4-404c-8454-5a64d81c8da0' User entered 'None (0)' | System           | 12 Sep 2020 02:28:01 |
|  | System           | 12 Sep 2020 02:28:01 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:32

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) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-11T21:27:20', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '532424bb-4aa4-404c-8454-5a64d81c8da0' User entered 'No (N)' | System           | 12 Sep 2020 02:28:01 |
|  | System           | 12 Sep 2020 02:28:01 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:32

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-11T21:27:24', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '532424bb-4aa4-404c-8454-5a64d81c8da0' User entered '11 Sep 2020 21:27' | System           | 12 Sep 2020 02:28:01 |
|   | System           | 12 Sep 2020 02:28:01 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '11 Sep 2020 12:00' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '12 Sep 2020 11:59' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.   | System           | 09 Sep 2020 15:52:25 |
| User entered 'Day 4' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:32

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-13T10:39:07', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '43b37239-f8b4-43d6-b7c7-f20ab343a32c' User entered 'None (0)' | System           | 13 Sep 2020 15:39:43 |
|  | System           | 13 Sep 2020 15:39:43 |



US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:32

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-13T10:39:09', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '43b37239-f8b4-43d6-b7c7-f20ab343a32c' User entered 'None (0)' | System           | 13 Sep 2020 15:39:43 |
|  | System           | 13 Sep 2020 15:39:43 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:32

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-13T10:39:12', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '43b37239-f8b4-43d6-b7c7-f20ab343a32c' User entered 'None (0)' | System           | 13 Sep 2020 15:39:43 |
|  | System           | 13 Sep 2020 15:39:43 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:32

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-13T10:39:14', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '43b37239-f8b4-43d6-b7c7-f20ab343a32c' User entered 'None (0)' | System           | 13 Sep 2020 15:39:43 |
|  | System           | 13 Sep 2020 15:39:43 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:32

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-13T10:39:18', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '43b37239-f8b4-43d6-b7c7-f20ab343a32c' User entered 'None (0)' | System           | 13 Sep 2020 15:39:43 |
|  | System           | 13 Sep 2020 15:39:43 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:32

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-13T10:39:21', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '43b37239-f8b4-43d6-b7c7-f20ab343a32c' User entered 'None (0)' | System           | 13 Sep 2020 15:39:43 |
|  | System           | 13 Sep 2020 15:39:43 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:32

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) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-13T10:39:28', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '43b37239-f8b4-43d6-b7c7-f20ab343a32c' User entered 'No (N)' | System           | 13 Sep 2020 15:39:43 |
|  | System           | 13 Sep 2020 15:39:43 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:32

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-13T10:39:31', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '43b37239-f8b4-43d6-b7c7-f20ab343a32c' User entered '13 Sep 2020 10:39' | System           | 13 Sep 2020 15:39:43 |
|   | System           | 13 Sep 2020 15:39:43 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '12 Sep 2020 12:00' | System           | 09 Sep 2020 15:52:25 |



US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '13 Sep 2020 11:59' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.   | System           | 09 Sep 2020 15:52:25 |
| User entered 'Day 5' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:32

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-13T21:36:17', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '85262e14-a28b-4f4c-b801-3ab567db4fcb' User entered 'None (0)' | System           | 14 Sep 2020 02:36:46 |
|  | System           | 14 Sep 2020 02:36:46 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:32

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-13T21:36:22', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '85262e14-a28b-4f4c-b801-3ab567db4fcb' User entered 'None (0)' | System           | 14 Sep 2020 02:36:46 |
|  | System           | 14 Sep 2020 02:36:46 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:32

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-13T21:36:25', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '85262e14-a28b-4f4c-b801-3ab567db4fcb' User entered 'None (0)' | System           | 14 Sep 2020 02:36:46 |
|  | System           | 14 Sep 2020 02:36:46 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:32

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-13T21:36:29', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '85262e14-a28b-4f4c-b801-3ab567db4fcb' User entered 'None (0)' | System           | 14 Sep 2020 02:36:46 |
|  | System           | 14 Sep 2020 02:36:46 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:32

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-13T21:36:32', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '85262e14-a28b-4f4c-b801-3ab567db4fcb' User entered 'None (0)' | System           | 14 Sep 2020 02:36:46 |
|  | System           | 14 Sep 2020 02:36:46 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:32

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-13T21:36:35', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '85262e14-a28b-4f4c-b801-3ab567db4fcb' User entered 'None (0)' | System           | 14 Sep 2020 02:36:46 |
|  | System           | 14 Sep 2020 02:36:46 |



US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:32

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) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-13T21:36:39', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '85262e14-a28b-4f4c-b801-3ab567db4fcb' User entered 'No (N)' | System           | 14 Sep 2020 02:36:46 |
|  | System           | 14 Sep 2020 02:36:46 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:32

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-13T21:36:42', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '85262e14-a28b-4f4c-b801-3ab567db4fcb' User entered '13 Sep 2020 21:36' | System           | 14 Sep 2020 02:36:46 |
|   | System           | 14 Sep 2020 02:36:46 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '13 Sep 2020 12:00' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '14 Sep 2020 11:59' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.   | System           | 09 Sep 2020 15:52:25 |
| User entered 'Day 6' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:32

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-14T12:35:31', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '7617344f-20a9-480b-a95c-56d689f92760' | System           | 14 Sep 2020 17:35:56 |
| User entered 'None (0)'  | System           | 14 Sep 2020 17:35:56 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:32

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-14T12:35:34', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '7617344f-20a9-480b-a95c-56d689f92760' | System           | 14 Sep 2020 17:35:56 |
| User entered 'None (0)'  | System           | 14 Sep 2020 17:35:56 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:32

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-14T12:35:38', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '7617344f-20a9-480b-a95c-56d689f92760' | System           | 14 Sep 2020 17:35:56 |
| User entered 'None (0)'  | System           | 14 Sep 2020 17:35:56 |



US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:32

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-14T12:35:40', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '7617344f-20a9-480b-a95c-56d689f92760' | System           | 14 Sep 2020 17:35:56 |
| User entered 'None (0)'  | System           | 14 Sep 2020 17:35:56 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:32

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-14T12:35:42', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '7617344f-20a9-480b-a95c-56d689f92760' | System           | 14 Sep 2020 17:35:56 |
| User entered 'None (0)'  | System           | 14 Sep 2020 17:35:56 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:32

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-14T12:35:45', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '7617344f-20a9-480b-a95c-56d689f92760' | System           | 14 Sep 2020 17:35:56 |
| User entered 'None (0)'  | System           | 14 Sep 2020 17:35:56 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:32

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) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-14T12:35:49', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '7617344f-20a9-480b-a95c-56d689f92760'<br>User entered 'No (N)' | System           | 14 Sep 2020 17:35:56 |
|   | System           | 14 Sep 2020 17:35:56 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:32

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-09-14T12:35:54', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '7617344f-20a9-480b-a95c-56d689f92760' User entered '14 Sep 2020 12:35' | System           | 14 Sep 2020 17:35:56 |
|   | System           | 14 Sep 2020 17:35:56 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '14 Sep 2020 12:00' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '15 Sep 2020 11:59' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.   | System           | 09 Sep 2020 15:52:25 |
| User entered 'Day 7' | System           | 09 Sep 2020 15:52:25 |



US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:32

**HEADACHE**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:32

**FATIGUE**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:32

**MUSCLE ACHES ALL OVER BODY**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:32

**JOINT ACHES IN SEVERAL JOINTS**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:32

**NAUSEA/VOMITING**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:32

**CHILLS**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:32

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) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:32

[PC Time stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |



US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '15 Sep 2020 12:00' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '16 Sep 2020 11:59' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:32

[Was Contact Attempted?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| User entered 'Yes (Y)'    | (b) (4)<br>Cindy Trimmer (b) (4) | 17 Sep 2020 13:37:14 |

US3422244

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:32

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded.  | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| User entered '16 Sep 2020' | (b) (4)<br>Cindy Trimmer (b) (4) | 17 Sep 2020 13:37:14 |
|                            | (b) (4)                          |                      |

US3422244

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:32

[Please select one status for the follow-up contact](#)

| Audit                                      | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded.                  | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Cindy Trimmer (b) (4) | 17 Sep 2020 13:37:14 |

US3422244

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:32

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| User entered empty.       | (b) (4)<br>Cindy Trimmer (b) (4) | 17 Sep 2020 13:37:14 |
|                           | (b) (4)                          |                      |

US3422244

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:32

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

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| User entered 'Yes (Y)'    | (b) (4)<br>Cindy Trimmer (b) (4) | 17 Sep 2020 18:29:31 |

US3422244

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:32

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| User entered '1'  | System           | 17 Sep 2020 18:29:31 |



US3422244

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:32

[Was Contact Attempted?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 24 Sep 2020 16:03:16 |

US3422244

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:32

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

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded.  | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| User entered '23 Sep 2020' | (b) (4)<br>(b) (4), (b) (6) | 24 Sep 2020 16:03:16 |

US3422244

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:32

[Please select one status for the follow-up contact](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded.                  | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>(b) (4), (b) (6) | 24 Sep 2020 16:03:16 |

US3422244

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:32

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 24 Sep 2020 16:03:16 |

US3422244

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:32

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 24 Sep 2020 16:03:22 |

US3422244

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:32

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| User entered '1'  | System           | 24 Sep 2020 16:03:22 |

US3422244

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:32

[Was Contact Attempted?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 07 Oct 2020 16:23:43 |

US3422244

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:32

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

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded.  | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| User entered '30 Sep 2020' | (b) (4)<br>(b) (4), (b) (6) | 07 Oct 2020 16:23:43 |



US3422244

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:32

[Please select one status for the follow-up contact](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded.                  | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>(b) (4), (b) (6) | 07 Oct 2020 16:23:43 |

US3422244

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:32

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 07 Oct 2020 16:23:43 |

US3422244

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:32

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 07 Oct 2020 16:23:49 |

US3422244

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:32

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| User entered '1'  | System           | 07 Oct 2020 16:23:49 |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:32

[Was this visit performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:40 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 07 Oct 2020 16:23:58 |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:32

Visit date (dd MMM yyyy)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:40 |
| User entered '7 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 07 Oct 2020 16:23:58 |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:32

[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 22:08:20 |
| User signature succeeded.      | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:40 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>(b) (4), (b) (6) | 07 Oct 2020 16:23:58 |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:32

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered 'VISIT2' | System           | 07 Oct 2020 16:23:58 |



US3422244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:32

[Timepoint](#)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.                                | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Cindy Trimmer (b) (4)<br>(b) (4) | 07 Oct 2020 17:49:40 |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:32

Were vital signs assessed?

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered 'Yes (Y)'    | (b) (4)<br>Cindy Trimmer (b) (4) | 07 Oct 2020 17:49:40 |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:32

Date of assessment (*dd MMM yyyy*)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '7 Oct 2020' | (b) (4)<br>Cindy Trimmer (b) (4) | 07 Oct 2020 17:49:40 |
|                           | (b) (4)                          |                      |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:32

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

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '11:09'      | (b) (4)<br>Cindy Trimmer (b) (4) | 07 Oct 2020 17:49:40 |
|                           | (b) (4)                          |                      |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:32

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

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered '7 Oct 2020 11:09' | System           | 07 Oct 2020 17:49:40 |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:32

Temperature (xxx.x)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '98.3' F     | (b) (4)<br>Cindy Trimmer (b) (4) | 07 Oct 2020 17:49:40 |
|                           | (b) (4)                          |                      |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:32

[Route of measurement](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded.  | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered 'Oral (Oral)' | (b) (4)<br>Cindy Trimmer (b) (4) | 07 Oct 2020 17:49:40 |
|                            | (b) (4)                          |                      |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:32

[If Other, specify](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered empty.       | (b) (4)<br>Cindy Trimmer (b) (4) | 07 Oct 2020 17:49:40 |
|                           | (b) (4)                          |                      |



US3422244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:32

[Pulse \(xxx\)](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '72'         | (b) (4)<br>Cindy Trimmer (b) (4) | 07 Oct 2020 17:49:40 |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:32

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered 'bpm' | System           | 07 Oct 2020 17:49:40 |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:32

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

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '16'         | (b) (4)<br>Cindy Trimmer (b) (4) | 07 Oct 2020 17:49:40 |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:32

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered 'breaths/min' | System           | 07 Oct 2020 17:49:40 |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:32

Systolic Blood Pressure (xxx)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '115'        | (b) (4)<br>Cindy Trimmer (b) (4) | 07 Oct 2020 17:49:40 |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:32

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered 'mmHg' | System           | 07 Oct 2020 17:49:40 |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:32

Diastolic Blood Pressure (xxx)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '71'         | (b) (4)<br>Cindy Trimmer (b) (4) | 07 Oct 2020 17:49:40 |
|                           | (b) (4)                          |                      |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:32

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered 'mmHg' | System           | 07 Oct 2020 17:49:40 |



US3422244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:32

[Timepoint](#)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Cindy Trimmer (b) (4)<br>(b) (4) | 07 Oct 2020 17:49:40 |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:32

Were vital signs assessed?

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered 'Yes (Y)'    | (b) (4)<br>Cindy Trimmer (b) (4) | 07 Oct 2020 17:49:40 |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:32

Date of assessment (*dd MMM yyyy*)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '7 Oct 2020' | (b) (4)<br>Cindy Trimmer (b) (4) | 07 Oct 2020 17:49:40 |
|                           | (b) (4)                          |                      |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:32

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

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '12:06'      | (b) (4)<br>Cindy Trimmer (b) (4) | 07 Oct 2020 17:49:40 |
|                           | (b) (4)                          |                      |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:32

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

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered '7 Oct 2020 12:06' | System           | 07 Oct 2020 17:49:40 |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:32

Temperature (xxx.x)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '98.1' F     | (b) (4)<br>Cindy Trimmer (b) (4) | 07 Oct 2020 17:49:40 |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:32

[Route of measurement](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded.  | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered 'Oral (Oral)' | (b) (4)<br>Cindy Trimmer (b) (4) | 07 Oct 2020 17:49:40 |
|                            | (b) (4)                          |                      |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:32

[If Other, specify](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered empty.       | (b) (4)<br>Cindy Trimmer (b) (4) | 07 Oct 2020 17:49:40 |
|                           | (b) (4)                          |                      |



US3422244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:32

[Pulse \(xxx\)](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '83'         | (b) (4)<br>Cindy Trimmer (b) (4) | 07 Oct 2020 17:49:40 |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:32

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered 'bpm' | System           | 07 Oct 2020 17:49:40 |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:32

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

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '14'         | (b) (4)<br>Cindy Trimmer (b) (4) | 07 Oct 2020 17:49:40 |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:32

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered 'breaths/min' | System           | 07 Oct 2020 17:49:40 |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:32

Systolic Blood Pressure (xxx)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '127'        | (b) (4)<br>Cindy Trimmer (b) (4) | 07 Oct 2020 17:49:40 |
|                           | (b) (4)                          |                      |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:32

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered 'mmHg' | System           | 07 Oct 2020 17:49:40 |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:32

Diastolic Blood Pressure (xxx)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '76'         | (b) (4)<br>Cindy Trimmer (b) (4) | 07 Oct 2020 17:49:40 |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:32

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered 'mmHg' | System           | 07 Oct 2020 17:49:40 |



US3422244

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:32

[Was the physical examination performed?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered 'Yes (Y)'    | (b) (4)<br>Cindy Trimmer (b) (4) | 07 Oct 2020 17:49:52 |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:32

Date of examination (dd MMM yyyy)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '7 Oct 2020' | (b) (4)<br>Cindy Trimmer (b) (4) | 07 Oct 2020 17:49:52 |
|                           | (b) (4)                          |                      |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:32

[Was study treatment given?](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)        | 27 Apr 2021 22:08:20 |
| User signature succeeded.   | Clarence Creech (b) (4) | 05 Mar 2021 18:38:40 |
| User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).             | System                  | 07 Oct 2020 16:41:16 |
| Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System). | System                  | 07 Oct 2020 16:41:16 |
| User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).             | System                  | 07 Oct 2020 16:24:10 |
| User entered 'Yes (Y)'  | (b) (4), (b) (6)        | 07 Oct 2020 16:24:10 |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:32

[If No, reason not given](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:40 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 07 Oct 2020 16:24:10 |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:32

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:40 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 07 Oct 2020 16:24:10 |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:32

[What was the study treatment?](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| Data hard locked.                   | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered 'MRNA-1273 OR PLACEBO' | System           | 07 Oct 2020 16:24:10 |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:32

What was the treatment date? (dd MMM yyyy)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:40 |
| User entered '7 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 07 Oct 2020 16:24:10 |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)        | 27 Apr 2021 22:08:20 |
| User signature succeeded.                                | Clarence Creech (b) (4) | 05 Mar 2021 18:38:40 |
| User entered '11:36' reason for change: Data Entry Error | (b) (4)                 | (b) (4), (b) (6)     |
| User entered empty.                                      | (b) (4), (b) (6)        | 07 Oct 2020 16:41:16 |
|  |                         | 07 Oct 2020 16:24:10 |



US3422244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:32

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

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered '7 Oct 2020 11:36' | System           | 07 Oct 2020 16:41:16 |
| User entered empty.             | System           | 07 Oct 2020 16:24:10 |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:32

Which arm was used to give treatment?

| Audit                              | User                        | Time (GMT)           |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded.          | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:40 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4)<br>(b) (4), (b) (6) | 07 Oct 2020 16:24:10 |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:32

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered 'ONCE' | System           | 07 Oct 2020 16:24:10 |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:32

What was the route of administration for the study treatment?

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered 'INTRAMUSCULAR' | System           | 07 Oct 2020 16:24:10 |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:32

[Was the sample collected?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered 'Yes (Y)'    | (b) (4)<br>Cindy Trimmer (b) (4) | 07 Oct 2020 17:50:01 |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:32

Collection date (dd MMM yyyy)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '7 Oct 2020' | (b) (4)<br>Cindy Trimmer (b) (4) | 07 Oct 2020 17:50:01 |
|                           | (b) (4)                          |                      |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:32

Collection time (00:00-23:59)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '11:15'      | (b) (4)<br>Cindy Trimmer (b) (4) | 07 Oct 2020 17:50:01 |
|                           | (b) (4)                          |                      |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:32

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

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered '7 Oct 2020 11:15' | System           | 07 Oct 2020 17:50:01 |



US3422244

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:34:32

Collection date (dd MMM yyyy)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered '7 Oct 2020' | (b) (4)<br>Cindy Trimmer (b) (4) | 07 Oct 2020 17:50:13 |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:34:32

[Lab Test](#)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Cindy Trimmer (b) (4)<br>(b) (4) | 07 Oct 2020 17:50:13 |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:34:32

[Was the sample collected?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered 'Yes (Y)'    | (b) (4)<br>Cindy Trimmer (b) (4) | 07 Oct 2020 17:50:13 |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:34:32

Collection time (00:00 - 23:59)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)                     | 05 Mar 2021 18:38:40 |
| User entered '11:12'      | (b) (4)<br>Cindy Trimmer (b) (4)<br>(b) (4) | 07 Oct 2020 17:50:13 |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:34:32

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

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered '7 Oct 2020 11:12' | System           | 07 Oct 2020 17:50:13 |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:34:32

[Lab Test](#)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Cindy Trimmer (b) (4)<br>(b) (4) | 07 Oct 2020 17:50:13 |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:34:32

[Was the sample collected?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered 'No (N)'     | (b) (4)<br>Cindy Trimmer (b) (4) | 07 Oct 2020 17:50:13 |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:34:32

Collection time (00:00 - 23:59)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered empty.       | (b) (4)<br>Cindy Trimmer (b) (4) | 07 Oct 2020 17:50:13 |
|                           | (b) (4)                          |                      |



US3422244

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:34:32

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered empty. | System           | 07 Oct 2020 17:50:13 |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:32

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

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:40 |
| User entered 'Yes (Y)'    | (b) (4)<br>Cindy Trimmer (b) (4) | 07 Oct 2020 17:50:19 |

US3422244

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:32

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered '1'  | System           | 07 Oct 2020 17:50:19 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.   | System           | 07 Oct 2020 16:41:16 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-07T12:08:58', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '2826b6da-25e6-4d15-a430-388fd0d510a1' User entered 'Yes (Y)' | System           | 07 Oct 2020 17:09:27 |
|   | System           | 07 Oct 2020 17:09:27 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-07T12:09:08', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '2826b6da-25e6-4d15-a430-388fd0d510a1' User entered '98.1' | System           | 07 Oct 2020 17:09:27 |
|  | System           | 07 Oct 2020 17:09:27 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-07T12:09:16', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '2826b6da-25e6-4d15-a430-388fd0d510a1' User entered 'No (N)' | System           | 07 Oct 2020 17:09:27 |
|  | System           | 07 Oct 2020 17:09:27 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-07T12:09:23', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '2826b6da-25e6-4d15-a430-388fd0d510a1' User entered '07 Oct 2020 12:09' | System           | 07 Oct 2020 17:09:27 |
|   | System           | 07 Oct 2020 17:09:27 |



US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '07 Oct 2020 11:56' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '07 Oct 2020 14:26' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.                                | System           | 07 Oct 2020 16:41:16 |
| User entered 'Day 1, after vaccination (at home)' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-07T21:24:48', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '1b727bc0-512b-4ab1-adcf-33c47a59e5aa' User entered 'Yes (Y)' | System           | 08 Oct 2020 02:25:24 |
|   | System           | 08 Oct 2020 02:25:24 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-07T21:24:58', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '1b727bc0-512b-4ab1-adcf-33c47a59e5aa' User entered '97.6' | System           | 08 Oct 2020 02:25:24 |
|  | System           | 08 Oct 2020 02:25:24 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-07T21:25:07', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '1b727bc0-512b-4ab1-adcf-33c47a59e5aa' | System           | 08 Oct 2020 02:25:24 |
| User entered 'No (N)'  | System           | 08 Oct 2020 02:25:24 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-07T21:25:23', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '1b727bc0-512b-4ab1-adcf-33c47a59e5aa' User entered '07 Oct 2020 21:25' | System           | 08 Oct 2020 02:25:24 |
|   | System           | 08 Oct 2020 02:25:24 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '07 Oct 2020 15:21' | System           | 07 Oct 2020 16:41:16 |



US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '08 Oct 2020 11:59' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.   | System           | 07 Oct 2020 16:41:16 |
| User entered 'Day 2' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:32

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-08T15:36:57', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '89e83542-e3fe-4886-89c5-397b45a2455d' User entered 'Yes (Y)' | System           | 08 Oct 2020 20:37:20 |
|   | System           | 08 Oct 2020 20:37:20 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:32

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-08T15:37:04', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '89e83542-e3fe-4886-89c5-397b45a2455d' User entered '98.1' | System           | 08 Oct 2020 20:37:20 |
|  | System           | 08 Oct 2020 20:37:20 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-08T15:37:09', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '89e83542-e3fe-4886-89c5-397b45a2455d' User entered 'No (N)' | System           | 08 Oct 2020 20:37:20 |
|  | System           | 08 Oct 2020 20:37:20 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:32

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-08T15:37:15', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '89e83542-e3fe-4886-89c5-397b45a2455d' User entered '08 Oct 2020 15:37' | System           | 08 Oct 2020 20:37:20 |
|   | System           | 08 Oct 2020 20:37:20 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '08 Oct 2020 12:00' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '09 Oct 2020 11:59' | System           | 07 Oct 2020 16:41:16 |



US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.   | System           | 07 Oct 2020 16:41:16 |
| User entered 'Day 3' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:32

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-10T04:35:08', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'b00dcf0a-3c8e-4b98-a59e-128c871f9cdd' User entered 'Yes (Y)' | System           | 10 Oct 2020 09:35:33 |
|   | System           | 10 Oct 2020 09:35:33 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:32

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-10T04:35:17', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'b00dcf0a-3c8e-4b98-a59e-128c871f9cdd' User entered '97.9' | System           | 10 Oct 2020 09:35:33 |
|  | System           | 10 Oct 2020 09:35:33 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-10T04:35:22', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'b00dcf0a-3c8e-4b98-a59e-128c871f9cdd' | System           | 10 Oct 2020 09:35:33 |
| User entered 'No (N)'  | System           | 10 Oct 2020 09:35:33 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:32

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-10T04:35:28', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'b00dcf0a-3c8e-4b98-a59e-128c871f9cdd' User entered '10 Oct 2020 04:35' | System           | 10 Oct 2020 09:35:33 |
|   | System           | 10 Oct 2020 09:35:33 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '09 Oct 2020 12:00' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '10 Oct 2020 11:59' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.   | System           | 07 Oct 2020 16:41:16 |
| User entered 'Day 4' | System           | 07 Oct 2020 16:41:16 |



US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:32

Was **TEMPERATURE** taken?

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:32

Please record your **TEMPERATURE** in °F

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:32

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:32

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:32

To **PREVENT** pain or fever from occurring

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:32

[PC Time Stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '10 Oct 2020 12:00' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '11 Oct 2020 11:59' | System           | 07 Oct 2020 16:41:16 |



US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.   | System           | 07 Oct 2020 16:41:16 |
| User entered 'Day 5' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:32

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-11T17:31:09', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '0c803a67-7708-4dae-8b05-b867968c9709' User entered 'Yes (Y)' | System           | 11 Oct 2020 22:31:34 |
|   | System           | 11 Oct 2020 22:31:34 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:32

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-11T17:31:19', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '0c803a67-7708-4dae-8b05-b867968c9709' User entered '98.2' | System           | 11 Oct 2020 22:31:34 |
|  | System           | 11 Oct 2020 22:31:34 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-11T17:31:24', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '0c803a67-7708-4dae-8b05-b867968c9709' | System           | 11 Oct 2020 22:31:34 |
| User entered 'No (N)'  | System           | 11 Oct 2020 22:31:34 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:32

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-11T17:31:27', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '0c803a67-7708-4dae-8b05-b867968c9709' User entered '11 Oct 2020 17:31' | System           | 11 Oct 2020 22:31:34 |
|   | System           | 11 Oct 2020 22:31:34 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '11 Oct 2020 12:00' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '12 Oct 2020 11:59' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.   | System           | 07 Oct 2020 16:41:16 |
| User entered 'Day 6' | System           | 07 Oct 2020 16:41:16 |



US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:32

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-12T13:50:19', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '1adc098b-26a6-4695-952e-4993fc946b7a' User entered 'Yes (Y)' | System           | 12 Oct 2020 18:50:48 |
|   | System           | 12 Oct 2020 18:50:48 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:32

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-12T13:50:36', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '1adc098b-26a6-4695-952e-4993fc946b7a' User entered '97.9' | System           | 12 Oct 2020 18:50:48 |
|  | System           | 12 Oct 2020 18:50:48 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-12T13:50:39', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '1adc098b-26a6-4695-952e-4993fc946b7a' | System           | 12 Oct 2020 18:50:48 |
| User entered 'No (N)'  | System           | 12 Oct 2020 18:50:48 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:32

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-12T13:50:45', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '1adc098b-26a6-4695-952e-4993fc946b7a' User entered '12 Oct 2020 13:50' | System           | 12 Oct 2020 18:50:48 |
|   | System           | 12 Oct 2020 18:50:48 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '12 Oct 2020 12:00' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '13 Oct 2020 11:59' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.   | System           | 07 Oct 2020 16:41:16 |
| User entered 'Day 7' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:32

Was **TEMPERATURE** taken?

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |



US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:32

Please record your **TEMPERATURE** in °F

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:32

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:32

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:32

To **PREVENT** pain or fever from occurring

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:32

[PC Time Stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '13 Oct 2020 12:00' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '14 Oct 2020 11:59' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.   | System           | 07 Oct 2020 16:41:16 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 07 Oct 2020 16:41:16 |



US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-07T12:09:34', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'b15812b7-e80d-4706-bc7c-4efb74e3b0da' | System           | 07 Oct 2020 17:09:58 |
| User entered 'None (1)'  | System           | 07 Oct 2020 17:09:58 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-07T12:09:40', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'b15812b7-e80d-4706-bc7c-4efb74e3b0da' | System           | 07 Oct 2020 17:09:58 |
| User entered 'No (N)'  | System           | 07 Oct 2020 17:09:58 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-07T12:09:47', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'b15812b7-e80d-4706-bc7c-4efb74e3b0da' User entered 'No (N)' | System           | 07 Oct 2020 17:09:58 |
|  | System           | 07 Oct 2020 17:09:58 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-07T12:09:52', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'b15812b7-e80d-4706-bc7c-4efb74e3b0da' | System           | 07 Oct 2020 17:09:58 |
| User entered 'None (1)'  | System           | 07 Oct 2020 17:09:58 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-07T12:09:55', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'b15812b7-e80d-4706-bc7c-4efb74e3b0da' User entered '07 Oct 2020 12:09' | System           | 07 Oct 2020 17:09:58 |
|   | System           | 07 Oct 2020 17:09:58 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '07 Oct 2020 11:56' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '07 Oct 2020 14:26' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.                                | System           | 07 Oct 2020 16:41:16 |
| User entered 'Day 1, after vaccination (at home)' | System           | 07 Oct 2020 16:41:16 |



US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-07T21:24:20', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'bbee44be-3a93-4db1-9398-5e16611d936c' | System           | 08 Oct 2020 02:24:38 |
| User entered 'None (1)'  | System           | 08 Oct 2020 02:24:38 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-07T21:24:24', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'bbee44be-3a93-4db1-9398-5e16611d936c' | System           | 08 Oct 2020 02:24:38 |
| User entered 'No (N)'  | System           | 08 Oct 2020 02:24:38 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-07T21:24:28', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'bbee44be-3a93-4db1-9398-5e16611d936c' | System           | 08 Oct 2020 02:24:38 |
| User entered 'No (N)'  | System           | 08 Oct 2020 02:24:38 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-07T21:24:33', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'bbee44be-3a93-4db1-9398-5e16611d936c' | System           | 08 Oct 2020 02:24:38 |
| User entered 'None (1)'  | System           | 08 Oct 2020 02:24:38 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-07T21:24:37', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'bbee44be-3a93-4db1-9398-5e16611d936c' User entered '07 Oct 2020 21:24' | System           | 08 Oct 2020 02:24:38 |
|   | System           | 08 Oct 2020 02:24:38 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '07 Oct 2020 15:21' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '08 Oct 2020 11:59' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.   | System           | 07 Oct 2020 16:41:16 |
| User entered 'Day 2' | System           | 07 Oct 2020 16:41:16 |



US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:32

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-08T15:37:24', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '6eaa475f-8d6f-48e0-aecb-817d4689da20' | System           | 08 Oct 2020 20:37:54 |
| User entered 'Does not interfere with activity (2)'  | System           | 08 Oct 2020 20:37:54 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-08T15:37:28', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '6eaa475f-8d6f-48e0-aecb-817d4689da20' | System           | 08 Oct 2020 20:37:54 |
| User entered 'No (N)'  | System           | 08 Oct 2020 20:37:54 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-08T15:37:35', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '6eaa475f-8d6f-48e0-aecb-817d4689da20' | System           | 08 Oct 2020 20:37:54 |
| User entered 'No (N)'  | System           | 08 Oct 2020 20:37:54 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:32

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-08T15:37:46', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '6eaa475f-8d6f-48e0-aecb-817d4689da20' | System           | 08 Oct 2020 20:37:54 |
| User entered 'None (1)'  | System           | 08 Oct 2020 20:37:54 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:32

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-08T15:37:53', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '6eaa475f-8d6f-48e0-aecb-817d4689da20' User entered '08 Oct 2020 15:37' | System           | 08 Oct 2020 20:37:54 |
|   | System           | 08 Oct 2020 20:37:54 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '08 Oct 2020 12:00' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '09 Oct 2020 11:59' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.   | System           | 07 Oct 2020 16:41:16 |
| User entered 'Day 3' | System           | 07 Oct 2020 16:41:16 |



US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:32

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-10T04:35:34', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '6932ea3c-01b6-4744-ab10-8f764992e01a' User entered 'None (1)' | System           | 10 Oct 2020 09:35:53 |
|  | System           | 10 Oct 2020 09:35:53 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-10T04:35:38', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '6932ea3c-01b6-4744-ab10-8f764992e01a' User entered 'No (N)' | System           | 10 Oct 2020 09:35:53 |
|  | System           | 10 Oct 2020 09:35:53 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-10T04:35:41', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '6932ea3c-01b6-4744-ab10-8f764992e01a' User entered 'No (N)' | System           | 10 Oct 2020 09:35:53 |
|  | System           | 10 Oct 2020 09:35:53 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:32

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-10T04:35:46', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '6932ea3c-01b6-4744-ab10-8f764992e01a' User entered 'None (1)' | System           | 10 Oct 2020 09:35:53 |
|  | System           | 10 Oct 2020 09:35:53 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:32

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-10T04:35:51', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '6932ea3c-01b6-4744-ab10-8f764992e01a' User entered '10 Oct 2020 04:35' | System           | 10 Oct 2020 09:35:53 |
|   | System           | 10 Oct 2020 09:35:53 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '09 Oct 2020 12:00' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '10 Oct 2020 11:59' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.   | System           | 07 Oct 2020 16:41:16 |
| User entered 'Day 4' | System           | 07 Oct 2020 16:41:16 |



US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:32

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

Please select one response below

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:32

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:32

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

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:32

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:32

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

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:32

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

Please select one response below

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:32

[PC Time Stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '10 Oct 2020 12:00' | System           | 07 Oct 2020 16:41:16 |



US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '11 Oct 2020 11:59' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.   | System           | 07 Oct 2020 16:41:16 |
| User entered 'Day 5' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:32

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-11T17:31:42', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'bc909df4-e845-49d0-9777-f0c4ced2d9fa' | System           | 11 Oct 2020 22:32:06 |
| User entered 'None (1)'  | System           | 11 Oct 2020 22:32:06 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-11T17:31:46', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'bc909df4-e845-49d0-9777-f0c4ced2d9fa' | System           | 11 Oct 2020 22:32:06 |
| User entered 'No (N)'  | System           | 11 Oct 2020 22:32:06 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-11T17:31:49', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'bc909df4-e845-49d0-9777-f0c4ced2d9fa' | System           | 11 Oct 2020 22:32:06 |
| User entered 'No (N)'  | System           | 11 Oct 2020 22:32:06 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:32

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-11T17:31:59', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'bc909df4-e845-49d0-9777-f0c4ced2d9fa' | System           | 11 Oct 2020 22:32:06 |
| User entered 'None (1)'  | System           | 11 Oct 2020 22:32:06 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:32

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-11T17:32:02', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'bc909df4-e845-49d0-9777-f0c4ced2d9fa' | System           | 11 Oct 2020 22:32:06 |
| User entered '11 Oct 2020 17:32'   | System           | 11 Oct 2020 22:32:06 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '11 Oct 2020 12:00' | System           | 07 Oct 2020 16:41:16 |



US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '12 Oct 2020 11:59' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.   | System           | 07 Oct 2020 16:41:16 |
| User entered 'Day 6' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:32

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-12T13:50:51', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'eafcc0de-c674-48e1-a23e-8b8ac68129d2' | System           | 12 Oct 2020 18:51:11 |
| User entered 'None (1)'  | System           | 12 Oct 2020 18:51:11 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-12T13:50:54', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'eafcc0de-c674-48e1-a23e-8b8ac68129d2' | System           | 12 Oct 2020 18:51:11 |
| User entered 'No (N)'  | System           | 12 Oct 2020 18:51:11 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-12T13:51:01', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'eafcc0de-c674-48e1-a23e-8b8ac68129d2' | System           | 12 Oct 2020 18:51:11 |
| User entered 'No (N)'  | System           | 12 Oct 2020 18:51:11 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:32

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-12T13:51:05', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'eafcc0de-c674-48e1-a23e-8b8ac68129d2' | System           | 12 Oct 2020 18:51:11 |
| User entered 'None (1)'  | System           | 12 Oct 2020 18:51:11 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:32

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-12T13:51:08', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'eafcc0de-c674-48e1-a23e-8b8ac68129d2' User entered '12 Oct 2020 13:51' | System           | 12 Oct 2020 18:51:11 |
|   | System           | 12 Oct 2020 18:51:11 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '12 Oct 2020 12:00' | System           | 07 Oct 2020 16:41:16 |



US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '13 Oct 2020 11:59' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.   | System           | 07 Oct 2020 16:41:16 |
| User entered 'Day 7' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:32

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

Please select one response below

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:32

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:32

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

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:32

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:32

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

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:32

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

Please select one response below

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |



US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:32

[PC Time Stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '13 Oct 2020 12:00' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '14 Oct 2020 11:59' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.   | System           | 07 Oct 2020 16:41:16 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

**HEADACHE**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

**FATIGUE**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

**MUSCLE ACHES ALL OVER BODY**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

**JOINT ACHES IN SEVERAL JOINTS**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |



US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

**NAUSEA/VOMITING**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

**CHILLS**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

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) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

[PC Time stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '07 Oct 2020 11:56' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '07 Oct 2020 14:26' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.                                | System           | 07 Oct 2020 16:41:16 |
| User entered 'Day 1, after vaccination (at home)' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-07T21:25:43', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '90d1835e-edbb-4346-9308-cc15c8cf7664' User entered 'None (0)' | System           | 08 Oct 2020 02:26:12 |
|  | System           | 08 Oct 2020 02:26:12 |



US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-07T21:25:48', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '90d1835e-edbb-4346-9308-cc15c8cf7664' User entered 'None (0)' | System           | 08 Oct 2020 02:26:12 |
|  | System           | 08 Oct 2020 02:26:12 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-07T21:25:52', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '90d1835e-edbb-4346-9308-cc15c8cf7664' User entered 'None (0)' | System           | 08 Oct 2020 02:26:12 |
|  | System           | 08 Oct 2020 02:26:12 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-07T21:25:55', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '90d1835e-edbb-4346-9308-cc15c8cf7664' User entered 'None (0)' | System           | 08 Oct 2020 02:26:12 |
|  | System           | 08 Oct 2020 02:26:12 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-07T21:25:59', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '90d1835e-edbb-4346-9308-cc15c8cf7664' User entered 'None (0)' | System           | 08 Oct 2020 02:26:12 |
|  | System           | 08 Oct 2020 02:26:12 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-07T21:26:02', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '90d1835e-edbb-4346-9308-cc15c8cf7664' User entered 'None (0)' | System           | 08 Oct 2020 02:26:12 |
|  | System           | 08 Oct 2020 02:26:12 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

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) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-07T21:26:08', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '90d1835e-edbb-4346-9308-cc15c8cf7664' User entered 'No (N)' | System           | 08 Oct 2020 02:26:12 |
|  | System           | 08 Oct 2020 02:26:12 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-07T21:26:11', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '90d1835e-edbb-4346-9308-cc15c8cf7664' User entered '07 Oct 2020 21:26' | System           | 08 Oct 2020 02:26:12 |
|   | System           | 08 Oct 2020 02:26:12 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '07 Oct 2020 15:21' | System           | 07 Oct 2020 16:41:16 |



US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '08 Oct 2020 11:59' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.   | System           | 07 Oct 2020 16:41:16 |
| User entered 'Day 2' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:32

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-08T15:38:00', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'e3e64ba7-5e43-4903-90df-a00a6957ba34' User entered 'None (0)' | System           | 08 Oct 2020 20:38:32 |
|  | System           | 08 Oct 2020 20:38:32 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:32

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-08T15:38:06', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'e3e64ba7-5e43-4903-90df-a00a6957ba34' | System           | 08 Oct 2020 20:38:32 |
| User entered 'No interference with activity (1)'   | System           | 08 Oct 2020 20:38:32 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:32

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-08T15:38:10', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'e3e64ba7-5e43-4903-90df-a00a6957ba34' | System           | 08 Oct 2020 20:38:32 |
| User entered 'None (0)'  | System           | 08 Oct 2020 20:38:32 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:32

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-08T15:38:16', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'e3e64ba7-5e43-4903-90df-a00a6957ba34' User entered 'None (0)' | System           | 08 Oct 2020 20:38:32 |
|  | System           | 08 Oct 2020 20:38:32 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:32

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-08T15:38:19', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'e3e64ba7-5e43-4903-90df-a00a6957ba34' User entered 'None (0)' | System           | 08 Oct 2020 20:38:32 |
|  | System           | 08 Oct 2020 20:38:32 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:32

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-08T15:38:21', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'e3e64ba7-5e43-4903-90df-a00a6957ba34' User entered 'None (0)' | System           | 08 Oct 2020 20:38:32 |
|  | System           | 08 Oct 2020 20:38:32 |



US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:32

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) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-08T15:38:27', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'e3e64ba7-5e43-4903-90df-a00a6957ba34' | System           | 08 Oct 2020 20:38:32 |
| User entered 'No (N)'  | System           | 08 Oct 2020 20:38:32 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:32

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-08T15:38:29', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'e3e64ba7-5e43-4903-90df-a00a6957ba34' User entered '08 Oct 2020 15:38' | System           | 08 Oct 2020 20:38:32 |
|   | System           | 08 Oct 2020 20:38:32 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '08 Oct 2020 12:00' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '09 Oct 2020 11:59' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.   | System           | 07 Oct 2020 16:41:16 |
| User entered 'Day 3' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:32

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-10T04:35:56', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '8e82e591-6889-4ad3-8ae4-add88bda936b' User entered 'None (0)' | System           | 10 Oct 2020 09:36:24 |
|  | System           | 10 Oct 2020 09:36:24 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:32

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-10T04:35:59', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '8e82e591-6889-4ad3-8ae4-add88bda936b' User entered 'None (0)' | System           | 10 Oct 2020 09:36:24 |
|  | System           | 10 Oct 2020 09:36:24 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:32

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-10T04:36:02', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '8e82e591-6889-4ad3-8ae4-add88bda936b' User entered 'None (0)' | System           | 10 Oct 2020 09:36:24 |
|  | System           | 10 Oct 2020 09:36:24 |



US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:32

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-10T04:36:07', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '8e82e591-6889-4ad3-8ae4-add88bda936b' User entered 'None (0)' | System           | 10 Oct 2020 09:36:24 |
|  | System           | 10 Oct 2020 09:36:24 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:32

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-10T04:36:10', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '8e82e591-6889-4ad3-8ae4-add88bda936b' User entered 'None (0)' | System           | 10 Oct 2020 09:36:24 |
|  | System           | 10 Oct 2020 09:36:24 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:32

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-10T04:36:13', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '8e82e591-6889-4ad3-8ae4-add88bda936b' User entered 'None (0)' | System           | 10 Oct 2020 09:36:24 |
|  | System           | 10 Oct 2020 09:36:24 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:32

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) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-10T04:36:17', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '8e82e591-6889-4ad3-8ae4-add88bda936b' User entered 'No (N)' | System           | 10 Oct 2020 09:36:24 |
|  | System           | 10 Oct 2020 09:36:24 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:32

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-10T04:36:20', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '8e82e591-6889-4ad3-8ae4-add88bda936b' User entered '10 Oct 2020 04:36' | System           | 10 Oct 2020 09:36:24 |
|   | System           | 10 Oct 2020 09:36:24 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '09 Oct 2020 12:00' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '10 Oct 2020 11:59' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.   | System           | 07 Oct 2020 16:41:16 |
| User entered 'Day 4' | System           | 07 Oct 2020 16:41:16 |



US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:32

**HEADACHE**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:32

**FATIGUE**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:32

**MUSCLE ACHES ALL OVER BODY**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:32

**JOINT ACHES IN SEVERAL JOINTS**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:32

**NAUSEA/VOMITING**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:32

**CHILLS**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:32

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) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:32

[PC Time stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |



US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '10 Oct 2020 12:00' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '11 Oct 2020 11:59' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.   | System           | 07 Oct 2020 16:41:16 |
| User entered 'Day 5' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:32

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-11T17:32:11', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'd2ecde1a-2df4-4609-9f6c-a777c42d1d7e' User entered 'None (0)' | System           | 11 Oct 2020 22:32:41 |
|  | System           | 11 Oct 2020 22:32:41 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:32

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-11T17:32:14', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'd2ecde1a-2df4-4609-9f6c-a777c42d1d7e' User entered 'None (0)' | System           | 11 Oct 2020 22:32:41 |
|  | System           | 11 Oct 2020 22:32:41 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:32

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-11T17:32:16', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'd2ecde1a-2df4-4609-9f6c-a777c42d1d7e' User entered 'None (0)' | System           | 11 Oct 2020 22:32:41 |
|  | System           | 11 Oct 2020 22:32:41 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:32

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-11T17:32:19', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'd2ecde1a-2df4-4609-9f6c-a777c42d1d7e' User entered 'None (0)' | System           | 11 Oct 2020 22:32:41 |
|  | System           | 11 Oct 2020 22:32:41 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:32

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-11T17:32:22', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'd2ecde1a-2df4-4609-9f6c-a777c42d1d7e' User entered 'None (0)' | System           | 11 Oct 2020 22:32:41 |
|  | System           | 11 Oct 2020 22:32:41 |



US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:32

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-11T17:32:25', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'd2ecde1a-2df4-4609-9f6c-a777c42d1d7e' User entered 'None (0)' | System           | 11 Oct 2020 22:32:41 |
|  | System           | 11 Oct 2020 22:32:41 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:32

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) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-11T17:32:36', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'd2ecde1a-2df4-4609-9f6c-a777c42d1d7e' User entered 'No (N)' | System           | 11 Oct 2020 22:32:41 |
|  | System           | 11 Oct 2020 22:32:41 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:32

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-11T17:32:39', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'd2ecde1a-2df4-4609-9f6c-a777c42d1d7e' User entered '11 Oct 2020 17:32' | System           | 11 Oct 2020 22:32:41 |
|   | System           | 11 Oct 2020 22:32:41 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '11 Oct 2020 12:00' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '12 Oct 2020 11:59' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.   | System           | 07 Oct 2020 16:41:16 |
| User entered 'Day 6' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:32

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-12T13:51:13', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'b6376e05-f822-434d-b6fd-4cbe38ec8ff2' | System           | 12 Oct 2020 18:51:39 |
| User entered 'None (0)'  | System           | 12 Oct 2020 18:51:39 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:32

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-12T13:51:16', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'b6376e05-f822-434d-b6fd-4cbe38ec8ff2' | System           | 12 Oct 2020 18:51:39 |
| User entered 'None (0)'  | System           | 12 Oct 2020 18:51:39 |



US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:32

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-12T13:51:19', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'b6376e05-f822-434d-b6fd-4cbe38ec8ff2' | System           | 12 Oct 2020 18:51:39 |
| User entered 'None (0)'  | System           | 12 Oct 2020 18:51:39 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:32

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-12T13:51:23', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'b6376e05-f822-434d-b6fd-4cbe38ec8ff2' | System           | 12 Oct 2020 18:51:39 |
| User entered 'None (0)'  | System           | 12 Oct 2020 18:51:39 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:32

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-12T13:51:27', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'b6376e05-f822-434d-b6fd-4cbe38ec8ff2' | System           | 12 Oct 2020 18:51:39 |
| User entered 'None (0)'  | System           | 12 Oct 2020 18:51:39 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:32

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-12T13:51:30', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'b6376e05-f822-434d-b6fd-4cbe38ec8ff2' | System           | 12 Oct 2020 18:51:39 |
| User entered 'None (0)'  | System           | 12 Oct 2020 18:51:39 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:32

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) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-12T13:51:33', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'b6376e05-f822-434d-b6fd-4cbe38ec8ff2' | System           | 12 Oct 2020 18:51:39 |
| User entered 'No (N)'  | System           | 12 Oct 2020 18:51:39 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:32

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-10-12T13:51:37', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'b6376e05-f822-434d-b6fd-4cbe38ec8ff2' | System           | 12 Oct 2020 18:51:39 |
| User entered '12 Oct 2020 13:51'   | System           | 12 Oct 2020 18:51:39 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '12 Oct 2020 12:00' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '13 Oct 2020 11:59' | System           | 07 Oct 2020 16:41:16 |



US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.   | System           | 07 Oct 2020 16:41:16 |
| User entered 'Day 7' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:32

**HEADACHE**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:32

**FATIGUE**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:32

**MUSCLE ACHES ALL OVER BODY**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:32

**JOINT ACHES IN SEVERAL JOINTS**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:32

**NAUSEA/VOMITING**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:32

**CHILLS**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:32

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) | 05 Mar 2021 06:01:14 |



US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:32

[PC Time stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:32

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '13 Oct 2020 12:00' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:32

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| User entered '14 Oct 2020 11:59' | System           | 07 Oct 2020 16:41:16 |

US3422244

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:32

[Was Contact Attempted?](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)              | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)       | 05 Mar 2021 18:38:37 |
| User entered 'Yes (Y)'    | (b) (4)<br>Wendy Winn (b) (4) | 15 Oct 2020 15:39:41 |

US3422244

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:32

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

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)              | 27 Apr 2021 22:08:09 |
| User signature succeeded.  | Clarence Creech (b) (4)       | 05 Mar 2021 18:38:37 |
| User entered '14 Oct 2020' | (b) (4)<br>Wendy Winn (b) (4) | 15 Oct 2020 15:39:41 |

US3422244

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:32

[Please select one status for the follow-up contact](#)

| Audit                                      | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)        | 27 Apr 2021 22:08:09 |
| User signature succeeded.                  | Clarence Creech (b) (4) | 05 Mar 2021 18:38:37 |
| User entered 'Contact Made (CONTACT MADE)' | Wendy Winn (b) (4)      | 15 Oct 2020 15:39:41 |

US3422244

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:32

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)              | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)       | 05 Mar 2021 18:38:37 |
| User entered empty.       | (b) (4)<br>Wendy Winn (b) (4) | 15 Oct 2020 15:39:41 |
|                           | (b) (4)                       |                      |

US3422244

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:32

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

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4) | 05 Mar 2021 18:38:37 |
| User entered 'Yes (Y)'    | Wendy Winn (b) (4)      | 15 Oct 2020 15:39:46 |



US3422244

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:32

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| User entered 'I'  | System           | 15 Oct 2020 15:39:46 |

US3422244

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:32

[Was Contact Attempted?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| User entered 'Yes (Y)'    | (b) (4)<br>Cindy Trimmer (b) (4) | 22 Oct 2020 14:07:33 |

US3422244

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:32

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded.  | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| User entered '21 Oct 2020' | (b) (4)<br>Cindy Trimmer (b) (4) | 22 Oct 2020 14:07:33 |
|                            | (b) (4)                          |                      |

US3422244

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:32

[Please select one status for the follow-up contact](#)

| Audit                                      | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded.                  | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Cindy Trimmer (b) (4) | 22 Oct 2020 14:07:33 |

US3422244

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:32

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| User entered empty.       | (b) (4)<br>Cindy Trimmer (b) (4) | 22 Oct 2020 14:07:33 |
|                           | (b) (4)                          |                      |

US3422244

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:32

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

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| User entered 'Yes (Y)'    | (b) (4)<br>Cindy Trimmer (b) (4) | 22 Oct 2020 14:07:26 |

US3422244

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:32

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| User entered '1'  | System           | 22 Oct 2020 14:07:26 |

US3422244

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:32

[Was Contact Attempted?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| User entered 'Yes (Y)'    | (b) (4)<br>Cindy Trimmer (b) (4) | 29 Oct 2020 14:34:59 |



US3422244

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:32

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded.  | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| User entered '28 Oct 2020' | (b) (4)<br>Cindy Trimmer (b) (4) | 29 Oct 2020 14:34:59 |
|                            | (b) (4)                          |                      |

US3422244

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:32

[Please select one status for the follow-up contact](#)

| Audit                                      | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded.                  | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Cindy Trimmer (b) (4) | 29 Oct 2020 14:34:59 |

US3422244

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:32

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| User entered empty.       | (b) (4)<br>Cindy Trimmer (b) (4) | 29 Oct 2020 14:34:59 |
|                           | (b) (4)                          |                      |

US3422244

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:32

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

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| User entered 'Yes (Y)'    | (b) (4)<br>Cindy Trimmer (b) (4) | 29 Oct 2020 14:34:48 |

US3422244

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:32

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| User entered '1'  | System           | 29 Oct 2020 14:34:48 |

US3422244

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:32

[Was this visit performed?](#)

| Audit   | User                          | Time (GMT)           |
|---|-------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)              | 27 Apr 2021 22:08:20 |
| User signature succeeded.   | Clarence Creech (b) (4)       | 05 Mar 2021 18:38:40 |
| User closed query 'Per CDM: Enter 'Vital Signs' under the Visit 3 Day 57 folder. Per page 34 of v4.0 of CCGs, 'Were vital signs assessed? Indicate Yes or No.' Thank you. ' (Site from DM).             | (b) (4)<br>(b) (4), (b) (6)   | 05 Feb 2021 11:33:44 |
| Query 'Per CDM: Enter 'Vital Signs' under the Visit 3 Day 57 folder. Per page 34 of v4.0 of CCGs, 'Were vital signs assessed? Indicate Yes or No.' Thank you. ' answered with 'changed' (Site from DM). | Naomi Kown (b) (4)<br>(b) (4) | 03 Feb 2021 19:16:05 |
| User closed query 'Was this visit performed is No, however Visit Date is provided. Please correct.' (Site from System).   | System                        | 03 Feb 2021 19:15:59 |
| User entered 'Yes (Y)' reason for change: Data Entry Error  | Naomi Kown (b) (4)<br>(b) (4) | 03 Feb 2021 19:15:59 |
| User opened query 'Was this visit performed is No, however Visit Date is provided. Please correct.' (Site from System).   | System                        | 03 Feb 2021 19:15:20 |
| User entered 'No (N)' reason for change: Data Entry Error   | Naomi Kown (b) (4)<br>(b) (4) | 03 Feb 2021 19:15:20 |
| User opened query 'Per CDM: Enter 'Vital Signs' under the Visit 3 Day 57 folder. Per page 34 of v4.0 of CCGs, 'Were vital signs assessed? Indicate Yes or No.' Thank you. ' (Site from DM).             | (b) (4), (b) (6)              | 01 Feb 2021 16:14:59 |
| User entered 'Yes (Y)'  | (b) (4), (b) (6)              | 04 Nov 2020 21:44:40 |

US3422244

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:32

Visit date (dd MMM yyyy)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:40 |
| User entered '4 Nov 2020' | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 21:44:40 |

US3422244

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:32

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 22:08:20 |
| User signature succeeded.   | Clarence Creech (b) (4) | 05 Mar 2021 18:38:40 |
| User closed query 'Visit was not performed, however, Was visit performed at home or clinic is provided. Please review and reconcile.' (Site from System). | (b) (4)                 | 03 Feb 2021 19:15:59 |
| User opened query 'Visit was not performed, however, Was visit performed at home or clinic is provided. Please review and reconcile.' (Site from System). | System                  | 03 Feb 2021 19:15:20 |
| User entered 'Clinic (Clinic)'  | (b) (4), (b) (6)        | 04 Nov 2020 21:44:40 |



US3422244

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:32

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered 'VISIT3' | System           | 04 Nov 2020 21:44:40 |

US3422244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:32

[Were vital signs assessed?](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)              | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)       | 05 Mar 2021 18:38:40 |
| User entered 'No (N)'     | (b) (4)<br>Naomi Kown (b) (4) | 03 Feb 2021 19:16:15 |

US3422244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:32

Date of assessment (*dd MMM yyyy*)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)              | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)       | 05 Mar 2021 18:38:40 |
| User entered empty.       | (b) (4)<br>Naomi Kown (b) (4) | 03 Feb 2021 19:16:15 |

US3422244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:32

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

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)              | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)       | 05 Mar 2021 18:38:40 |
| User entered empty.       | (b) (4)<br>Naomi Kown (b) (4) | 03 Feb 2021 19:16:15 |

US3422244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:32

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered empty. | System           | 03 Feb 2021 19:16:15 |

US3422244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:32

Temperature (xxx.x)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)              | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)       | 05 Mar 2021 18:38:40 |
| User entered empty.       | (b) (4)<br>Naomi Kown (b) (4) | 03 Feb 2021 19:16:15 |

US3422244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:32

[Route of measurement](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)              | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)       | 05 Mar 2021 18:38:40 |
| User entered empty.       | (b) (4)<br>Naomi Kown (b) (4) | 03 Feb 2021 19:16:15 |

US3422244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:32

[If Other, specify](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)              | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)       | 05 Mar 2021 18:38:40 |
| User entered empty.       | (b) (4)<br>Naomi Kown (b) (4) | 03 Feb 2021 19:16:15 |



US3422244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:32

[Pulse \(xxx\)](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)              | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)       | 05 Mar 2021 18:38:40 |
| User entered empty.       | (b) (4)<br>Naomi Kown (b) (4) | 03 Feb 2021 19:16:15 |

US3422244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:32

[Pulse units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered empty. | System           | 03 Feb 2021 19:16:15 |

US3422244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:32

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

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)              | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)       | 05 Mar 2021 18:38:40 |
| User entered empty.       | (b) (4)<br>Naomi Kown (b) (4) | 03 Feb 2021 19:16:15 |

US3422244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:32

[Respiratory Rate units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered empty. | System           | 03 Feb 2021 19:16:15 |

US3422244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:32

Systolic Blood Pressure (xxx)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)              | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)       | 05 Mar 2021 18:38:40 |
| User entered empty.       | (b) (4)<br>Naomi Kown (b) (4) | 03 Feb 2021 19:16:15 |

US3422244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:32

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered empty. | System           | 03 Feb 2021 19:16:15 |

US3422244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:32

Diastolic Blood Pressure (xxx)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)              | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)       | 05 Mar 2021 18:38:40 |
| User entered empty.       | (b) (4)<br>Naomi Kown (b) (4) | 03 Feb 2021 19:16:15 |

US3422244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:32

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered empty. | System           | 03 Feb 2021 19:16:15 |



US3422244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:32

[Height \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |

US3422244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:32

[Weight \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |

US3422244

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:32

[Was the physical examination performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:40 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 21:44:52 |

US3422244

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:32

Date of examination (dd MMM yyyy)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:40 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 21:44:52 |

US3422244

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:32

[Was the sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:40 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 21:45:14 |

US3422244

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:32

Collection date (dd MMM yyyy)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:40 |
| User entered '4 Nov 2020' | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 21:45:14 |

US3422244

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:32

Collection time (00:00-23:59)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:40 |
| User entered '13:35'      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 21:45:14 |

US3422244

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:32

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

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered '4 Nov 2020 13:35' | System           | 04 Nov 2020 21:45:14 |



US3422244

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:32

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:20 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:40 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 21:45:27 |

US3422244

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:32

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 22:08:20 |
| User entered '1'  | System           | 04 Nov 2020 21:45:27 |

US3422244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.    | System           | 09 Sep 2020 15:52:25 |
| User entered 'Day 64' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-11-09T10:43:21', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '332ac61e-73c2-4f97-9095-f31486e88490' | System           | 09 Nov 2020 16:43:39 |
| User entered 'No (N)'  | System           | 09 Nov 2020 16:43:39 |

US3422244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-11-09T10:43:26', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '332ac61e-73c2-4f97-9095-f31486e88490' | System           | 09 Nov 2020 16:43:39 |
| User entered 'No (N)'  | System           | 09 Nov 2020 16:43:39 |

US3422244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

[Date and time of submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-11-09T10:43:37', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '332ac61e-73c2-4f97-9095-f31486e88490' User entered '09 Nov 2020 10:43:37' | System           | 09 Nov 2020 16:43:39 |
|  | System           | 09 Nov 2020 16:43:39 |

US3422244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

[Patient Cloud Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.               | System           | 09 Sep 2020 15:52:25 |
| User entered '09 Nov 2020 00:01' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

[Patient Cloud Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.               | System           | 09 Sep 2020 15:52:25 |
| User entered '13 Nov 2020 23:59' | System           | 09 Sep 2020 15:52:25 |



US3422244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.    | System           | 09 Sep 2020 15:52:25 |
| User entered 'Day 71' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-11-16T10:58:18', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'de6c3200-ef78-4d39-8355-f8b04762ddc2' | System           | 16 Nov 2020 16:58:34 |
| User entered 'No (N)'  | System           | 16 Nov 2020 16:58:34 |

US3422244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-11-16T10:58:23', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'de6c3200-ef78-4d39-8355-f8b04762ddc2' | System           | 16 Nov 2020 16:58:34 |
| User entered 'No (N)'  | System           | 16 Nov 2020 16:58:34 |

US3422244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

[Date and time of submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-11-16T10:58:31', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'de6c3200-ef78-4d39-8355-f8b04762ddc2' User entered '16 Nov 2020 10:58:31' | System           | 16 Nov 2020 16:58:34 |
|  | System           | 16 Nov 2020 16:58:34 |

US3422244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

[Patient Cloud Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.               | System           | 09 Sep 2020 15:52:25 |
| User entered '16 Nov 2020 00:01' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

[Patient Cloud Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 06:01:14 |
| Data entry locked.               | System           | 09 Sep 2020 15:52:25 |
| User entered '20 Nov 2020 23:59' | System           | 09 Sep 2020 15:52:25 |

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                                    | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| Amendment Manager: Data entry locked.    | System           | 20 Nov 2020 06:33:47 |
| Amendment Manager: User entered 'Day 75' | System           | 20 Nov 2020 06:33:47 |

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-11-20T17:14:48', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'd80e8879-3f1a-43b6-bed8-66df3c769d5e' | System           | 20 Nov 2020 23:15:07 |
| User entered 'No (N)'  | System           | 20 Nov 2020 23:15:07 |



US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-11-20T17:14:56', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'd80e8879-3f1a-43b6-bed8-66df3c769d5e' | System           | 20 Nov 2020 23:15:07 |
| User entered 'No (N)'  | System           | 20 Nov 2020 23:15:07 |

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

[Date and time of submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-11-20T17:15:04', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'd80e8879-3f1a-43b6-bed8-66df3c769d5e' User entered '20 Nov 2020 17:15:04' | System           | 20 Nov 2020 23:15:07 |
|  | System           | 20 Nov 2020 23:15:07 |

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

[Patient Cloud Open Date & Time](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                   | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| Amendment Manager: Data entry locked.               | System           | 20 Nov 2020 06:33:47 |
| Amendment Manager: User entered '20 Nov 2020 00:01' | System           | 20 Nov 2020 06:33:47 |

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

[Patient Cloud Close Date & Time](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                   | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| Amendment Manager: Data entry locked.               | System           | 20 Nov 2020 06:33:47 |
| Amendment Manager: User entered '24 Nov 2020 23:59' | System           | 20 Nov 2020 06:33:47 |

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                                    | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| Amendment Manager: Data entry locked.    | System           | 20 Nov 2020 06:33:47 |
| Amendment Manager: User entered 'Day 82' | System           | 20 Nov 2020 06:33:47 |

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-11-29T09:11:23', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '5a243e51-2e4e-4410-a1e3-2a0eb4b27fd5' | System           | 29 Nov 2020 15:11:47 |
| User entered 'No (N)'  | System           | 29 Nov 2020 15:11:47 |

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-11-29T09:11:28', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '5a243e51-2e4e-4410-a1e3-2a0eb4b27fd5' | System           | 29 Nov 2020 15:11:47 |
| User entered 'No (N)'  | System           | 29 Nov 2020 15:11:47 |

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

[Date and time of submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-11-29T09:11:44', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '5a243e51-2e4e-4410-a1e3-2a0eb4b27fd5' User entered '29 Nov 2020 09:11:44' | System           | 29 Nov 2020 15:11:47 |
|  | System           | 29 Nov 2020 15:11:47 |



US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

[Patient Cloud Open Date & Time](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                   | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| Amendment Manager: Data entry locked.               | System           | 20 Nov 2020 06:33:47 |
| Amendment Manager: User entered '27 Nov 2020 00:01' | System           | 20 Nov 2020 06:33:47 |

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

[Patient Cloud Close Date & Time](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                   | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| Amendment Manager: Data entry locked.               | System           | 20 Nov 2020 06:33:47 |
| Amendment Manager: User entered '01 Dec 2020 23:59' | System           | 20 Nov 2020 06:33:47 |

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                                    | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| Amendment Manager: Data entry locked.    | System           | 20 Nov 2020 06:33:47 |
| Amendment Manager: User entered 'Day 89' | System           | 20 Nov 2020 06:33:47 |

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-12-05T12:09:45', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '9bf6de3b-b827-4350-a821-88783f9b35af' User entered 'No (N)' | System           | 05 Dec 2020 18:10:05 |
|  | System           | 05 Dec 2020 18:10:05 |

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-12-05T12:09:54', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '9bf6de3b-b827-4350-a821-88783f9b35af' | System           | 05 Dec 2020 18:10:05 |
| User entered 'No (N)'  | System           | 05 Dec 2020 18:10:05 |

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

[Date and time of submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-12-05T12:10:00', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '9bf6de3b-b827-4350-a821-88783f9b35af' User entered '05 Dec 2020 12:10:00' | System           | 05 Dec 2020 18:10:05 |
|  | System           | 05 Dec 2020 18:10:05 |

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

[Patient Cloud Open Date & Time](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                   | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| Amendment Manager: Data entry locked.               | System           | 20 Nov 2020 06:33:47 |
| Amendment Manager: User entered '04 Dec 2020 00:01' | System           | 20 Nov 2020 06:33:47 |

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

[Patient Cloud Close Date & Time](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                   | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| Amendment Manager: Data entry locked.               | System           | 20 Nov 2020 06:33:47 |
| Amendment Manager: User entered '08 Dec 2020 23:59' | System           | 20 Nov 2020 06:33:47 |



US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                                    | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| Amendment Manager: Data entry locked.    | System           | 20 Nov 2020 06:33:47 |
| Amendment Manager: User entered 'Day 96' | System           | 20 Nov 2020 06:33:47 |

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-12-14T13:15:14', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'b406d77f-1bcd-4e32-aa7d-8bdfb3c692b0' | System           | 14 Dec 2020 19:15:44 |
| User entered 'No (N)'  | System           | 14 Dec 2020 19:15:44 |

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-12-14T13:15:25', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'b406d77f-1bcd-4e32-aa7d-8bdfb3c692b0' | System           | 14 Dec 2020 19:15:44 |
| User entered 'No (N)'  | System           | 14 Dec 2020 19:15:44 |

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

[Date and time of submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-12-14T13:15:31', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'b406d77f-1bcd-4e32-aa7d-8bdfb3c692b0' User entered '14 Dec 2020 13:15:31' | System           | 14 Dec 2020 19:15:44 |
|  | System           | 14 Dec 2020 19:15:44 |

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

[Patient Cloud Open Date & Time](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                   | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| Amendment Manager: Data entry locked.               | System           | 20 Nov 2020 06:33:47 |
| Amendment Manager: User entered '11 Dec 2020 00:01' | System           | 20 Nov 2020 06:33:47 |

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

[Patient Cloud Close Date & Time](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                   | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| Amendment Manager: Data entry locked.               | System           | 20 Nov 2020 06:33:47 |
| Amendment Manager: User entered '15 Dec 2020 23:59' | System           | 20 Nov 2020 06:33:47 |

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| Amendment Manager: Data entry locked.     | System           | 20 Nov 2020 06:33:47 |
| Amendment Manager: User entered 'Day 103' | System           | 20 Nov 2020 06:33:47 |

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-12-19T17:34:36', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'cc6a36ef-0840-4c63-b8a2-39e41f8861dd' | System           | 19 Dec 2020 23:34:55 |
| User entered 'No (N)'  | System           | 19 Dec 2020 23:34:55 |



US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-12-19T17:34:41', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'cc6a36ef-0840-4c63-b8a2-39e41f8861dd' | System           | 19 Dec 2020 23:34:55 |
| User entered 'No (N)'  | System           | 19 Dec 2020 23:34:55 |

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

[Date and time of submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-12-19T17:34:52', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'cc6a36ef-0840-4c63-b8a2-39e41f8861dd' User entered '19 Dec 2020 17:34:52' | System           | 19 Dec 2020 23:34:55 |
|  | System           | 19 Dec 2020 23:34:55 |

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

[Patient Cloud Open Date & Time](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                   | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| Amendment Manager: Data entry locked.               | System           | 20 Nov 2020 06:33:47 |
| Amendment Manager: User entered '18 Dec 2020 00:01' | System           | 20 Nov 2020 06:33:47 |

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

[Patient Cloud Close Date & Time](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                   | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| Amendment Manager: Data entry locked.               | System           | 20 Nov 2020 06:33:47 |
| Amendment Manager: User entered '22 Dec 2020 23:59' | System           | 20 Nov 2020 06:33:47 |

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| Amendment Manager: Data entry locked.     | System           | 20 Nov 2020 06:33:47 |
| Amendment Manager: User entered 'Day 110' | System           | 20 Nov 2020 06:33:47 |

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-12-26T10:07:16', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '5cd5b674-43cb-40ab-8f6a-9adcd986ca98' | System           | 26 Dec 2020 16:07:27 |
| User entered 'No (N)'  | System           | 26 Dec 2020 16:07:27 |

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-12-26T10:07:19', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '5cd5b674-43cb-40ab-8f6a-9adcd986ca98' | System           | 26 Dec 2020 16:07:27 |
| User entered 'No (N)'  | System           | 26 Dec 2020 16:07:27 |

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

[Date and time of submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2020-12-26T10:07:23', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: '5cd5b674-43cb-40ab-8f6a-9adcd986ca98' User entered '26 Dec 2020 10:07:23' | System           | 26 Dec 2020 16:07:27 |
|  | System           | 26 Dec 2020 16:07:27 |



US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

[Patient Cloud Open Date & Time](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                   | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| Amendment Manager: Data entry locked.               | System           | 20 Nov 2020 06:33:47 |
| Amendment Manager: User entered '25 Dec 2020 00:01' | System           | 20 Nov 2020 06:33:47 |

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

[Patient Cloud Close Date & Time](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                   | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| Amendment Manager: Data entry locked.               | System           | 20 Nov 2020 06:33:47 |
| Amendment Manager: User entered '29 Dec 2020 23:59' | System           | 20 Nov 2020 06:33:47 |

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

**TIMEPOINT**

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| Amendment Manager: Data entry locked.     | System           | 20 Nov 2020 06:33:47 |
| Amendment Manager: User entered 'Day 117' | System           | 20 Nov 2020 06:33:47 |

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2021-01-01T09:12:57', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'e81ec318-190b-4a79-85ba-d1f4a79f37ee' | System           | 01 Jan 2021 15:13:10 |
| User entered 'No (N)'  | System           | 01 Jan 2021 15:13:10 |

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2021-01-01T09:13:02', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'e81ec318-190b-4a79-85ba-d1f4a79f37ee' | System           | 01 Jan 2021 15:13:10 |
| User entered 'No (N)'  | System           | 01 Jan 2021 15:13:10 |

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

[Date and time of submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6ADCDBF4-BD5D-4A62-83CC-F080D1884CB6)', Time: '2021-01-01T09:13:07', User OID: 'PatientReportedOutcome (US3422244)', ODM File OID: 'e81ec318-190b-4a79-85ba-d1f4a79f37ee' User entered '01 Jan 2021 09:13:07' | System           | 01 Jan 2021 15:13:10 |
|  | System           | 01 Jan 2021 15:13:10 |

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

[Patient Cloud Open Date & Time](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                   | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| Amendment Manager: Data entry locked.               | System           | 20 Nov 2020 06:33:47 |
| Amendment Manager: User entered '01 Jan 2021 00:01' | System           | 20 Nov 2020 06:33:47 |

US3422244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:32

[Patient Cloud Close Date & Time](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                   | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| Amendment Manager: Data entry locked.               | System           | 20 Nov 2020 06:33:47 |
| Amendment Manager: User entered '05 Jan 2021 23:59' | System           | 20 Nov 2020 06:33:47 |



US3422244

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:32

[Was Contact Attempted?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4) | 05 Mar 2021 18:38:37 |
| User entered 'Yes (Y)'    | Cindy Trimmer (b) (4)   | 03 Dec 2020 19:46:53 |

US3422244

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:32

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

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| User entered '2 Dec 2020' | (b) (4)<br>Cindy Trimmer (b) (4) | 03 Dec 2020 19:46:53 |

US3422244

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:32

[Please select one status for the follow-up contact](#)

| Audit                                      | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded.                  | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Cindy Trimmer (b) (4) | 03 Dec 2020 19:46:53 |

US3422244

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:32

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| User entered empty.       | (b) (4)<br>Cindy Trimmer (b) (4) | 03 Dec 2020 19:46:53 |
|                           | (b) (4)                          |                      |

US3422244

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:32

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

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4) | 05 Mar 2021 18:38:37 |
| User entered 'Yes (Y)'    | Cindy Trimmer (b) (4)   | 03 Dec 2020 19:46:43 |

US3422244

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:32

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| User entered '1'  | System           | 03 Dec 2020 19:46:43 |

US3422244

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:34:32

[Did the participant experience any adverse events?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 20:06:34 |
| User entered 'Yes (Y)'    | Cindy Trimmer (b) (4)<br>(b) (4) | 21 Jan 2021 20:23:41 |

US3422244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:32

[AEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.                                     | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded.                             | Clarence Creech (b) (4)     | 28 Mar 2021 13:36:56 |
| Reviewed for Safety.                                  | (b) (4)<br>(b) (4), (b) (6) | 24 Mar 2021 20:00:36 |
| DataPoint Verified.                                   | (b) (4), (b) (6)            | 02 Feb 2021 20:08:25 |
| User entered<br>'USA-US082-2021-mRNA-1273-P301000004' | System                      | 22 Jan 2021 15:46:04 |
| User entered 'New'                                    | (b) (4), (b) (6)            | 22 Jan 2021 15:46:04 |



US3422244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:32

[Adverse event](#)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded.  | Clarence Creech (b) (4)          | 28 Mar 2021 13:36:56 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 20:08:25 |
| User coded data point as SOC: Cardiac disorders,<br>HLGT: Cardiac arrhythmias, HLT: Ventricular<br>arrhythmias and cardiac arrest, PT: Cardiac arrest,<br>LLT: Cardiac arrest - version MedDRA\23.0. | Coder Import (b) (4)<br>(b) (4)  | 21 Jan 2021 20:28:08 |
| User coded data point as Term Coded data point by<br>User: Coder System - version MedDRA\23.0.   | Coder Import (b) (4)<br>(b) (4)  | 21 Jan 2021 20:28:08 |
| Data point term sent to Coder  | System                           | 21 Jan 2021 20:26:45 |
| User entered 'Cardiac Arrest'  | Cindy Trimmer (b) (4)<br>(b) (4) | 21 Jan 2021 20:26:44 |

US3422244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:32

[Was this a medically-attended AE?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 28 Mar 2021 13:36:56 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 20:08:25 |
| User entered 'No (N)'     | Cindy Trimmer (b) (4)<br>(b) (4) | 21 Jan 2021 20:26:44 |

US3422244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:32

[Was this a Solicited Adverse Reaction?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 28 Mar 2021 13:36:56 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 20:08:25 |
| User entered 'No (N)'     | Cindy Trimmer (b) (4)<br>(b) (4) | 21 Jan 2021 20:26:44 |

US3422244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 28 Mar 2021 13:36:56 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 20:08:25 |
| User entered 'No (N)'     | Cindy Trimmer (b) (4)<br>(b) (4) | 21 Jan 2021 20:26:44 |

US3422244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:32

Start date (dd MMM yyyy)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded.  | Clarence Creech (b) (4)          | 28 Mar 2021 13:36:56 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 20:08:25 |
| User entered '03 Jan 2021' | Cindy Trimmer (b) (4)<br>(b) (4) | 21 Jan 2021 20:26:44 |

US3422244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:32

Start time (00:00-23:59)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 28 Mar 2021 13:36:56 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 20:08:25 |
| User entered empty.       | Cindy Trimmer (b) (4)<br>(b) (4) | 21 Jan 2021 20:26:44 |

US3422244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:32

[AE start date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| User entered empty. | System           | 21 Jan 2021 20:26:44 |

US3422244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:32

[Ongoing?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 28 Mar 2021 13:36:56 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 20:08:25 |
| User entered 'No (N)'     | Cindy Trimmer (b) (4)<br>(b) (4) | 21 Jan 2021 20:26:44 |



US3422244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:32

If not Ongoing, end date (dd MMM yyyy)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded.  | Clarence Creech (b) (4)          | 28 Mar 2021 13:36:56 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 20:08:25 |
| User entered '03 Jan 2021' | Cindy Trimmer (b) (4)<br>(b) (4) | 21 Jan 2021 20:26:44 |

US3422244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:32

End time (00:00-23:59)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 28 Mar 2021 13:36:56 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 20:08:25 |
| User entered empty.       | Cindy Trimmer (b) (4)<br>(b) (4) | 21 Jan 2021 20:26:44 |

US3422244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:32

[AE End Date and Time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| User entered empty. | System           | 21 Jan 2021 20:26:44 |

US3422244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:32

[Severity](#)

| Audit                            | User                             | Time (GMT)           |
|----------------------------------|----------------------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded.        | Clarence Creech (b) (4)          | 28 Mar 2021 13:36:56 |
| DataPoint Verified.              | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 20:08:25 |
| User entered 'Grade 4 (Grade 4)' | Cindy Trimmer (b) (4)<br>(b) (4) | 21 Jan 2021 20:26:44 |

US3422244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:32

[Is the adverse event serious?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 28 Mar 2021 13:36:56 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 20:08:25 |
| User entered 'Yes (Y)'    | Cindy Trimmer (b) (4)<br>(b) (4) | 21 Jan 2021 20:26:44 |

US3422244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:32

[Death](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 28 Mar 2021 13:36:56 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 20:08:25 |
| User entered '1'          | Cindy Trimmer (b) (4)<br>(b) (4) | 21 Jan 2021 20:26:44 |

US3422244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:32

[Life threatening](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 28 Mar 2021 13:36:56 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 20:08:25 |
| User entered '0'          | Cindy Trimmer (b) (4)<br>(b) (4) | 21 Jan 2021 20:26:44 |

US3422244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:32

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 28 Mar 2021 13:36:56 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 20:08:25 |
| User entered '0'          | Cindy Trimmer (b) (4)<br>(b) (4) | 21 Jan 2021 20:26:44 |



US3422244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:32

Hospital Admission Date (*dd MMM yyyy*)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 28 Mar 2021 13:36:56 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 20:08:25 |
| User entered empty.       | Cindy Trimmer (b) (4)<br>(b) (4) | 21 Jan 2021 20:26:44 |

US3422244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:32

Hospital Discharge Date (*dd MMM yyyy*)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 28 Mar 2021 13:36:56 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 20:08:25 |
| User entered empty.       | Cindy Trimmer (b) (4)<br>(b) (4) | 21 Jan 2021 20:26:44 |

US3422244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:32

[Admitted to ICU?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 28 Mar 2021 13:36:56 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 20:08:25 |
| User entered empty.       | Cindy Trimmer (b) (4)<br>(b) (4) | 21 Jan 2021 20:26:44 |

US3422244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:32

[Number of Days in ICU](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 28 Mar 2021 13:36:56 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 20:08:25 |
| User entered empty.       | Cindy Trimmer (b) (4)<br>(b) (4) | 21 Jan 2021 20:26:44 |

US3422244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:32

[Persistent or significant disability or incapacity](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 28 Mar 2021 13:36:56 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 20:08:25 |
| User entered '0'          | Cindy Trimmer (b) (4)<br>(b) (4) | 21 Jan 2021 20:26:44 |

US3422244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:32

[Congenital anomaly or birth defect](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 28 Mar 2021 13:36:56 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 20:08:25 |
| User entered '0'          | Cindy Trimmer (b) (4)<br>(b) (4) | 21 Jan 2021 20:26:44 |

US3422244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:32

[Other medically important event](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 28 Mar 2021 13:36:56 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 20:08:25 |
| User entered '0'          | Cindy Trimmer (b) (4)<br>(b) (4) | 21 Jan 2021 20:26:44 |

US3422244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:32

[Relationship to investigational product](#)

| Audit                                    | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded.                | Clarence Creech (b) (4)          | 28 Mar 2021 13:36:56 |
| DataPoint Verified.                      | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 20:08:25 |
| User entered 'Not Related (NOT RELATED)' | Cindy Trimmer (b) (4)<br>(b) (4) | 21 Jan 2021 20:26:44 |



US3422244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:32

[Relationship to Study Procedure](#)

| Audit   | User                          | Time (GMT)           |
|---|-------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)              | 27 Apr 2021 22:08:09 |
| User signature succeeded.   | Clarence Creech (b) (4)       | 28 Mar 2021 13:36:56 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)   | 17 Mar 2021 16:12:20 |
| User closed query 'PV Query: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Since the subject received the study drug this should be Related or Not Related. Please update accordingly.' (Site from Safety).               | (b) (4), (b) (6)              | 04 Feb 2021 17:33:27 |
| User closed query 'Per CDM: Relationship to IP is recorded as Not Related but Relationship to Study Procedure is recorded as Not Applicable. Please review and reconcile Relationship to Study Procedure.' (Site from DM).  | (b) (4), (b) (6)              | 04 Feb 2021 13:12:32 |
| Query 'PV Query: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Since the subject received the study drug this should be Related or Not Related. Please update accordingly.' answered with 'corrected' (Site from Safety). | Naomi Kown (b) (4)<br>(b) (4) | 03 Feb 2021 19:14:38 |
| Query 'Per CDM: Relationship to IP is recorded as Not Related but Relationship to Study Procedure is recorded as Not Applicable. Please review and reconcile Relationship to Study Procedure.' answered with 'corrected' (Site from DM).  | Naomi Kown (b) (4)<br>(b) (4) | 03 Feb 2021 19:14:32 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error  | Naomi Kown (b) (4)<br>(b) (4) | 03 Feb 2021 19:14:16 |
| DataPoint Un-verified.  | (b) (4), (b) (6)              | 02 Feb 2021 20:10:33 |
| DataPoint Verified.   | (b) (4), (b) (6)              | 02 Feb 2021 20:08:25 |

US3422244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:32

[Relationship to Study Procedure](#)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| User opened query 'PV Query: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Since the subject received the study drug this should be Related or Not Related. Please update accordingly.' (Site from Safety). | (b) (4), (b) (6)                 | 29 Jan 2021 16:31:07 |
| User opened query 'Per CDM: Relationship to IP is recorded as Not Related but Relationship to Study Procedure is recorded as Not Applicable. Please review and reconcile Relationship to Study Procedure.' (Site from DM).  | (b) (4), (b) (6)                 | 29 Jan 2021 14:29:44 |
| User entered 'Not Applicable (NOT APPLICABLE)'  | Cindy Trimmer (b) (4)<br>(b) (4) | 21 Jan 2021 20:26:44 |

US3422244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:32

Action taken with investigational product

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded.  | Clarence Creech (b) (4)     | 28 Mar 2021 13:36:56 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 17 Mar 2021 16:12:21 |
| User closed query 'PV Query: As the last dose of [study drug] was given on 07 Oct 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).               | (b) (4), (b) (6)            | 04 Feb 2021 17:33:35 |
| User closed query 'Per CDM: Subject received both doses of IP but Action taken with IP is None. Please review and update.' (Site from DM).   | (b) (4), (b) (6)            | 04 Feb 2021 13:12:59 |
| Query 'PV Query: As the last dose of [study drug] was given on 07 Oct 2020, please update the action taken with study drug from none to not applicable.' answered with 'corrected' (Site from Safety). | Naomi Kown (b) (4)          | 03 Feb 2021 19:14:46 |
| User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error   | Naomi Kown (b) (4)          | 03 Feb 2021 19:14:16 |
| DataPoint Un-verified.   | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:10:31 |
| DataPoint Verified.  | (b) (4), (b) (6)            | 02 Feb 2021 20:08:25 |
| User opened query 'PV Query: As the last dose of [study drug] was given on 07 Oct 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).               | (b) (4), (b) (6)            | 29 Jan 2021 16:29:47 |
| Query 'Per CDM: Subject received both doses of IP but Action taken with IP is None. Please review and update.' answered with 'N/A' (Site from DM).   | April Hanlotxomphou (b) (4) | 29 Jan 2021 16:27:45 |
| User opened query 'Per CDM: Subject received both doses of IP but Action taken with IP is None. Please review and update.' (Site from DM).   | (b) (4), (b) (6)            | 29 Jan 2021 14:30:18 |
| User entered 'None (NONE)'   | Cindy Trimmer (b) (4)       | 21 Jan 2021 20:26:44 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:32

[None](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 28 Mar 2021 13:36:56 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 20:08:25 |
| User entered '1'          | Cindy Trimmer (b) (4)<br>(b) (4) | 21 Jan 2021 20:26:44 |

US3422244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:32

[Concomitant Medication](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 28 Mar 2021 13:36:56 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 20:08:25 |
| User entered '0'          | Cindy Trimmer (b) (4)<br>(b) (4) | 21 Jan 2021 20:26:44 |

US3422244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:32

[Concomitant Procedure](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 28 Mar 2021 13:36:56 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 20:08:25 |
| User entered '0'          | Cindy Trimmer (b) (4)<br>(b) (4) | 21 Jan 2021 20:26:44 |

US3422244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:32

[Outcome](#)

| Audit                        | User                             | Time (GMT)           |
|------------------------------|----------------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded.    | Clarence Creech (b) (4)          | 28 Mar 2021 13:36:56 |
| DataPoint Verified.          | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 20:08:25 |
| User entered 'Fatal (FATAL)' | Cindy Trimmer (b) (4)<br>(b) (4) | 21 Jan 2021 20:26:44 |

US3422244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 28 Mar 2021 13:36:56 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 20:08:25 |
| User entered empty.       | Cindy Trimmer (b) (4)<br>(b) (4) | 21 Jan 2021 20:26:44 |



US3422244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:32

[Narrative](#)

| Audit  | User                          | Time (GMT)           |
|--|-------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)              | 27 Apr 2021 22:08:09 |
| User signature succeeded.  | Clarence Creech (b) (4)       | 28 Mar 2021 13:36:56 |
| User closed query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, when available. Please leave query unanswered until results are sent or, if unable to obtain, please state so.' (Site from Safety).   | (b) (4)<br>(b) (4), (b) (6)   | 24 Mar 2021 20:00:28 |
| Query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, when available. Please leave query unanswered until results are sent or, if unable to obtain, please state so.' answered with 'multiple attempts to contact next of kin, and no response' (Site from Safety). | Naomi Kown (b) (4)<br>(b) (4) | 23 Mar 2021 16:05:33 |
| User opened query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, when available. Please leave query unanswered until results are sent or, if unable to obtain, please state so.' (Site from Safety).   | (b) (4), (b) (6)              | 22 Mar 2021 19:04:28 |
| User closed query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, when available.' (Site from Safety).  | (b) (4), (b) (6)              | 22 Mar 2021 19:04:28 |
| Query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, when available.' answered with 'autopsy report still pending, multiple contacts made to next of kin.' (Site from Safety).   | Naomi Kown (b) (4)<br>(b) (4) | 19 Mar 2021 14:44:45 |
| DataPoint Verified.  | (b) (4), (b) (6)              | 17 Mar 2021 16:14:31 |
| User opened query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, when available.' (Site from Safety).  | (b) (4), (b) (6)              | 12 Feb 2021 03:01:45 |

US3422244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:32

[Narrative](#)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| User closed query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. If not performed, please state so.' (Site from Safety).  | (b) (4), (b) (6)                 | 04 Feb 2021 17:33:39 |
| Query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. If not performed, please state so.' answered with 'we are still waiting for autopsy results' (Site from Safety). | Naomi Kown (b) (4)<br>(b) (4)    | 03 Feb 2021 19:12:09 |
| DataPoint Un-verified.  | (b) (4), (b) (6)                 | 02 Feb 2021 20:10:16 |
| DataPoint Verified.   | (b) (4), (b) (6)                 | 02 Feb 2021 20:08:25 |
| User opened query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. If not performed, please state so.' (Site from Safety).  | (b) (4), (b) (6)                 | 29 Jan 2021 16:30:19 |
| User entered 'Participant found deceased from presumed cardiac arrest by spouse. Toxicology and autopsy report pending. No medical records available since participant died at home. Last contact via e-diary done from participant was 01JAN2021 and reported no issues.'                | Cindy Trimmer (b) (4)<br>(b) (4) | 21 Jan 2021 20:26:44 |

US3422244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:32

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| User entered '1'  | System           | 21 Jan 2021 20:26:44 |

US3422244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:32

Medically Attended AE Derived (CSA Programming Field Only)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| User entered '0'  | System           | 21 Jan 2021 20:26:44 |

US3422244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:32

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |

US3422244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:34:32

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 16:56:33 |
| User entered 'Yes (Y)'    | Cindy Trimmer (b) (4)<br>(b) (4) | 09 Sep 2020 17:13:12 |

US3422244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:32

Name of Medication

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded.  | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 20:15:32 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\202003. | Coder Import (b) (4)<br>(b) (4)  | 11 Nov 2020 20:06:35 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.   | Coder Import (b) (4)<br>(b) (4)  | 11 Nov 2020 20:06:35 |
| Data point term sent to Coder  | System                           | 11 Nov 2020 20:06:22 |
| Coding entries removed.  | Wendy Winn (b) (4)<br>(b) (4)    | 11 Nov 2020 20:05:52 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\202003. | Coder Import (b) (4)<br>(b) (4)  | 09 Sep 2020 17:15:42 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.   | Coder Import (b) (4)<br>(b) (4)  | 09 Sep 2020 17:15:42 |
| Data point term sent to Coder  | System                           | 09 Sep 2020 17:14:21 |
| User entered 'Gabapentin'  | Cindy Trimmer (b) (4)<br>(b) (4) | 09 Sep 2020 17:13:50 |

US3422244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:32

[Prophylaxis](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 20:15:32 |
| User entered 'No (N)'     | Cindy Trimmer (b) (4)<br>(b) (4) | 09 Sep 2020 17:13:50 |



US3422244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:32

[Indication](#)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded.  | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 20:15:32 |
| User closed query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match. '<br>(Site from DM).                          | (b) (4), (b) (6)                 | 01 Dec 2020 08:16:43 |
| Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match. '<br>answered with 'this as been updated' (Site from DM). | Wendy Winn (b) (4)<br>(b) (4)    | 11 Nov 2020 20:06:01 |
| User entered 'OSTEOARTHRITIS' reason for change: Data Entry Error  | Wendy Winn (b) (4)<br>(b) (4)    | 11 Nov 2020 20:05:52 |
| User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match. '<br>(Site from DM).                          | (b) (4), (b) (6)                 | 21 Oct 2020 09:04:44 |
| User entered 'Arthritis'   | Cindy Trimmer (b) (4)<br>(b) (4) | 09 Sep 2020 17:13:50 |

US3422244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:32

[Dose per administration](#)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded.  | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 20:15:32 |
| User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).             | (b) (4), (b) (6)                 | 01 Dec 2020 08:16:46 |
| Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated' (Site from DM). | (b) (4), (b) (6)                 | 12 Nov 2020 21:04:42 |
| User entered '300' reason for change: New Information  | (b) (4), (b) (6)                 | 12 Nov 2020 21:04:32 |
| User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).             | (b) (4), (b) (6)                 | 21 Oct 2020 09:04:54 |
| User entered '18'  | Cindy Trimmer (b) (4)<br>(b) (4) | 09 Sep 2020 17:13:50 |

US3422244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:32

[Dose unit](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 20:15:32 |
| User entered 'mg (mg)'    | Cindy Trimmer (b) (4)<br>(b) (4) | 09 Sep 2020 17:13:50 |

US3422244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:32

If dose unit is Other, specify

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 20:15:32 |
| User entered empty.       | Cindy Trimmer (b) (4)<br>(b) (4) | 09 Sep 2020 17:13:50 |

US3422244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:32

[Frequency](#)

| Audit                          | User                             | Time (GMT)           |
|--------------------------------|----------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded.      | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 20:15:32 |
| User entered 'as needed (PRN)' | Cindy Trimmer (b) (4)<br>(b) (4) | 09 Sep 2020 17:13:50 |

US3422244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:32

If frequency is Other, specify

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 20:15:32 |
| User entered empty.       | Cindy Trimmer (b) (4)<br>(b) (4) | 09 Sep 2020 17:13:50 |

US3422244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:32

[Route of administration](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded.  | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 20:15:32 |
| User entered 'Oral (ORAL)' | Cindy Trimmer (b) (4)<br>(b) (4) | 09 Sep 2020 17:13:50 |

US3422244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:32

If route of administration is Other, specify

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 20:15:32 |
| User entered empty.       | Cindy Trimmer (b) (4)<br>(b) (4) | 09 Sep 2020 17:13:50 |



US3422244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:32

Start date (dd MMM yyyy)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded.   | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)      | 28 Feb 2021 18:07:10 |
| User closed query 'Please confirm if date of medication start date is 1Jan2020 as subject was diagnosed for osteoarthritis in 1975. ' (Site from CRA).  | (b) (4), (b) (6)                 | 28 Feb 2021 18:07:08 |
| Query 'Please confirm if date of medication start date is 1Jan2020 as subject was diagnosed for osteoarthritis in 1975. ' answered with 'That is the reported date from the patient. ' (Site from CRA). | Anna Gallion (b) (4)<br>(b) (4)  | 02 Feb 2021 20:47:20 |
| User opened query 'Please confirm if date of medication start date is 1Jan2020 as subject was diagnosed for osteoarthritis in 1975. ' (Site from CRA).  | (b) (4), (b) (6)                 | 02 Feb 2021 20:17:05 |
| DataPoint Un-verified.  | (b) (4), (b) (6)                 | 02 Feb 2021 20:16:06 |
| DataPoint Verified.   | (b) (4), (b) (6)                 | 02 Feb 2021 20:15:32 |
| User entered '01 Jan 2020'  | Cindy Trimmer (b) (4)<br>(b) (4) | 09 Sep 2020 17:13:50 |

US3422244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:32

[Start date completely unknown](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 20:15:32 |
| User entered '0'          | Cindy Trimmer (b) (4)<br>(b) (4) | 09 Sep 2020 17:13:50 |

US3422244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:32

[Ongoing?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 20:15:32 |
| User entered 'Yes (Y)'    | Cindy Trimmer (b) (4)<br>(b) (4) | 09 Sep 2020 17:13:50 |

US3422244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:32

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 20:15:32 |
| User entered empty.       | Cindy Trimmer (b) (4)<br>(b) (4) | 09 Sep 2020 17:13:50 |

US3422244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:32

[Was this medication taken for solicited event?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 02 Feb 2021 20:15:32 |
| User entered 'No (N)'     | Cindy Trimmer (b) (4)<br>(b) (4) | 09 Sep 2020 17:13:50 |

US3422244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:32

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| User entered empty. | System           | 09 Sep 2020 17:13:50 |

US3422244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:32

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| User entered empty. | System           | 09 Sep 2020 17:13:50 |

US3422244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:32

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| User entered empty. | System           | 09 Sep 2020 17:13:50 |



US3422244

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:34:32

[Were any concomitant procedures performed?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| User entered 'No (N)'     | (b) (4)<br>Cindy Trimmer (b) (4) | 09 Sep 2020 17:13:57 |

US3422244

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:34:32

Date of study discontinuation/completion (*dd MMM yyyy*)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                 | 27 Apr 2021 14:21:31 |
| User signature succeeded.  | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| User closed query 'Date of Study Discontinuation/Completion is after Date of Death. Please correct.' (Site from System). | (b) (4)<br>System                | 21 Jan 2021 20:30:33 |
| User entered '03 Jan 2021' reason for change: Data Entry Error   | Cindy Trimmer (b) (4)<br>(b) (4) | 21 Jan 2021 20:30:33 |
| User opened query 'Date of Study Discontinuation/Completion is after Date of Death. Please correct.' (Site from System). | System                           | 21 Jan 2021 20:30:11 |
| User entered '21 Jan 2021'   | Cindy Trimmer (b) (4)<br>(b) (4) | 21 Jan 2021 20:30:11 |

US3422244

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:34:32

[Reason for discontinuation](#)

| Audit                        | User                             | Time (GMT)           |
|------------------------------|----------------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)                 | 27 Apr 2021 14:21:31 |
| User signature succeeded.    | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| User entered 'Death (DEATH)' | (b) (4)<br>Cindy Trimmer (b) (4) | 21 Jan 2021 20:30:11 |
|                              | (b) (4)                          |                      |

US3422244

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:34:32

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

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 14:21:31 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| User entered empty.       | (b) (4)<br>Cindy Trimmer (b) (4) | 21 Jan 2021 20:30:11 |
|                           | (b) (4)                          |                      |

US3422244

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:34:32

If reason for discontinuation is Death, main cause of death

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                 | 27 Apr 2021 14:21:31 |
| User signature succeeded.   | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| User closed query 'Per CDM: Per page 52 of v4.0 of CCGs, 'If death was caused by an adverse event, the same adverse event must be recorded in the adverse event section.' Please verify data and update as appropriate. Thank you.' (Site from DM).   | (b) (4)<br>(b) (4), (b) (6)      | 05 Feb 2021 11:49:28 |
| Query 'Per CDM: Per page 52 of v4.0 of CCGs, 'If death was caused by an adverse event, the same adverse event must be recorded in the adverse event section.' Please verify data and update as appropriate. Thank you.' answered with 'It is recorded in adverse event section. ' (Site from DM). | Anna Gallion (b) (4)<br>(b) (4)  | 01 Feb 2021 20:12:23 |
| User opened query 'Per CDM: Per page 52 of v4.0 of CCGs, 'If death was caused by an adverse event, the same adverse event must be recorded in the adverse event section.' Please verify data and update as appropriate. Thank you.' (Site from DM).   | (b) (4), (b) (6)                 | 01 Feb 2021 16:07:16 |
| User entered 'Adverse event (ADVERSE EVENT)'  | Cindy Trimmer (b) (4)<br>(b) (4) | 21 Jan 2021 20:30:11 |

US3422244

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:34:32

If main cause of death is Other, specify

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 14:21:31 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| User entered empty.       | (b) (4)<br>Cindy Trimmer (b) (4) | 21 Jan 2021 20:30:11 |
|                           | (b) (4)                          |                      |

US3422244

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:34:32

Date of death (*dd MMM yyyy*)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 14:21:31 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| User entered '3 Jan 2021' | (b) (4)<br>Cindy Trimmer (b) (4) | 21 Jan 2021 20:30:11 |
|                           | (b) (4)                          |                      |

US3422244

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:34:32

[Was autopsy performed?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 14:21:31 |
| User signature succeeded. | Clarence Creech (b) (4)          | 05 Mar 2021 18:38:37 |
| User entered 'Yes (Y)'    | (b) (4)<br>Cindy Trimmer (b) (4) | 21 Jan 2021 20:30:11 |



US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.                                     | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded.                             | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.                                   | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.                                  | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered<br>'USA-US082-2021-MRNA-1273-P301000004' | System                      | 22 Jan 2021 15:46:04 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

Serious

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered 'Yes (Y)'    | System                      | 22 Jan 2021 15:46:04 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

Death

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered 'Yes (Y)'    | System                      | 22 Jan 2021 15:46:04 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered 'No (N)'     | System                      | 22 Jan 2021 15:46:04 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered 'No (N)'     | System                      | 22 Jan 2021 15:46:04 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered 'No (N)'     | System                      | 22 Jan 2021 15:46:04 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered 'No (N)'     | System                      | 22 Jan 2021 15:46:04 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered 'No (N)'     | System                      | 22 Jan 2021 15:46:04 |



US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered 'Clarence'   | System                      | 22 Jan 2021 15:46:04 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered 'Creech'     | System                      | 22 Jan 2021 15:46:04 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

Site Address: Street

| Audit                       | User                        | Time (GMT)           |
|-----------------------------|-----------------------------|----------------------|
| Data hard locked.           | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded.   | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.         | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.        | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered 'CCC-5311 MCN' | System                      | 22 Jan 2021 15:46:04 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

Site Address: City

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered 'Nashville'  | System                      | 22 Jan 2021 15:46:04 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

Site Address: State

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered 'TN'         | System                      | 22 Jan 2021 15:46:04 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

Site Address: Postal Code

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered '37027'      | System                      | 22 Jan 2021 15:46:04 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered 'US'         | System                      | 22 Jan 2021 15:46:23 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| User entered '2'  | System           | 04 Feb 2021 17:37:19 |
| User entered '1'  | System           | 22 Jan 2021 15:46:23 |



US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.                                     | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded.                             | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.                                   | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.                                  | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered<br>'USA-US082-2021-MRNA-1273-P301000004' | System                      | 22 Jan 2021 15:46:04 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

Serious

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered 'Yes (Y)'    | System                      | 22 Jan 2021 15:46:04 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

Death

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered 'Yes (Y)'    | System                      | 22 Jan 2021 15:46:04 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered 'No (N)'     | System                      | 22 Jan 2021 15:46:04 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered 'No (N)'     | System                      | 22 Jan 2021 15:46:04 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered 'No (N)'     | System                      | 22 Jan 2021 15:46:04 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered 'No (N)'     | System                      | 22 Jan 2021 15:46:04 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered 'No (N)'     | System                      | 22 Jan 2021 15:46:04 |



US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered 'Clarence'   | System                      | 22 Jan 2021 15:46:04 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered 'Creech'     | System                      | 22 Jan 2021 15:46:04 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

Site Address: Street

| Audit                       | User                        | Time (GMT)           |
|-----------------------------|-----------------------------|----------------------|
| Data hard locked.           | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded.   | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.         | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.        | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered 'CCC-5311 MCN' | System                      | 22 Jan 2021 15:46:04 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

Site Address: City

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered 'Nashville'  | System                      | 22 Jan 2021 15:46:04 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

Site Address: State

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered 'TN'         | System                      | 22 Jan 2021 15:46:04 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

Site Address: Postal Code

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered '37027'      | System                      | 22 Jan 2021 15:46:04 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered 'US'         | System                      | 22 Jan 2021 15:46:23 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| User entered '2'  | System           | 04 Feb 2021 17:37:19 |
| User entered '1'  | System           | 22 Jan 2021 15:46:23 |



US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:34:32

Date of submission (Pre-filled from custom function)

| Audit                            | User                        | Time (GMT)           |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded.        | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.              | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| User entered '22/Jan/2021 10:46' | System                      | 22 Jan 2021 15:46:23 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:34:32

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered 'I'          | (b) (4), (b) (6)            | 22 Jan 2021 15:46:23 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.                                     | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded.                             | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.                                   | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.                                  | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered<br>'USA-US082-2021-MRNA-1273-P301000004' | System                      | 22 Jan 2021 15:46:04 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

Serious

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered 'Yes (Y)'    | System                      | 22 Jan 2021 15:46:04 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered 'Yes (Y)'    | System                      | 22 Jan 2021 15:46:04 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered 'No (N)'     | System                      | 22 Jan 2021 15:46:04 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered 'No (N)'     | System                      | 22 Jan 2021 15:46:04 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered 'No (N)'     | System                      | 22 Jan 2021 15:46:04 |



US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered 'No (N)'     | System                      | 22 Jan 2021 15:46:04 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered 'No (N)'     | System                      | 22 Jan 2021 15:46:04 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered 'Clarence'   | System                      | 22 Jan 2021 15:46:04 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered 'Creech'     | System                      | 22 Jan 2021 15:46:04 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

Site Address: Street

| Audit                       | User                        | Time (GMT)           |
|-----------------------------|-----------------------------|----------------------|
| Data hard locked.           | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded.   | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.         | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.        | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered 'CCC-5311 MCN' | System                      | 22 Jan 2021 15:46:04 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

Site Address: City

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered 'Nashville'  | System                      | 22 Jan 2021 15:46:04 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

Site Address: State

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered 'TN'         | System                      | 22 Jan 2021 15:46:04 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

Site Address: Postal Code

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered '37027'      | System                      | 22 Jan 2021 15:46:04 |



US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 20:06:26 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 22 Jan 2021 15:48:00 |
| User entered 'US'         | System                      | 22 Jan 2021 15:46:23 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 22:08:09 |
| User entered '2'  | System           | 04 Feb 2021 17:37:19 |
| User entered '1'  | System           | 22 Jan 2021 15:46:23 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:34:32

Date of submission (Pre-filled from custom function)

| Audit                            | User                    | Time (GMT)           |
|----------------------------------|-------------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6)        | 27 Apr 2021 22:08:09 |
| User signature succeeded.        | Clarence Creech (b) (4) | 05 Mar 2021 18:38:37 |
| User entered '04/Feb/2021 12:37' | (b) (4)<br>System       | 04 Feb 2021 17:37:19 |

US3422244

Folder: SAE USA-US082-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:34:32

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 22:08:09 |
| User signature succeeded. | Clarence Creech (b) (4)     | 05 Mar 2021 18:38:37 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 17:37:29 |
| User entered '1'          | (b) (4), (b) (6)            | 04 Feb 2021 17:37:19 |