

US3402139 (Prod: Meridian Clinical Research, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:26:34

All time stamps listed in this document are displayed in GMT

US3402139

Form: Participant Creation

Data signed: (b) (4) 26 Apr 2021 01:45:45

Generated On: 09 Jun 2021 17:26:34

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[Participant ID](#)

US3402139

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

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US3402139

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 16:53:15

Generated On: 09 Jun 2021 17:26:34

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 01 AUG 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | SCRN                                    |

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 16:53:15

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|   |  |
|---|--|
| Date of Birth (MMM yyyy)                  | (b) (6) 1965   |
| Age                                       | 55   |
| Age Units                                 | YEARS  |
| Age (Derived)                             | 55   |
| Sex                                       | Female <input checked="" type="radio"/><br>Male <input 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) 15 Feb 2021 16:53:15

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|   |  |
|---|--|
| Date of Informed Consent ( <i>dd MMM yyyy</i> ) | 01 AUG 2020                                  |
| Month and Year of Informed Consent (derived)    | AUG 2020                                     |
| Year of Informed Consent (derived)              | 2020   |
| Protocol Version                                | Amendment 1 <input checked="" type="radio"/> |
|   | Amendment 2 <input type="radio"/>            |
|   | Amendment 3 <input type="radio"/>            |
|   | Amendment 4 <input type="radio"/>            |
|   | Amendment 5 <input type="radio"/>            |
| Was participant enrolled in the study?          | Yes <input checked="" type="radio"/>         |
|   | No <input type="radio"/>                     |
| If No, indicate reason for screen fail          | Withdrew Consent <input type="radio"/>       |
|   | Inclusion/Exclusion <input type="radio"/>    |
|   | Cohort Full <input type="radio"/>            |
|   | Other <input type="radio"/>                  |
| If reason for screen fail is Other, specify     |  |
| Was this participant screened previously?       | Yes <input type="radio"/>                    |
|   | No <input checked="" type="radio"/>          |
| If Yes, previous participant number             |  |
| Enrollment Trigger                              | 1  |

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 16:53:15

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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) 15 Feb 2021 16:53:15

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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) 15 Feb 2021 16:53:15

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|   |  |
|---|--|
| Condition   | ENVIRONMENTAL ALLERGIES  |
| Start date (dd MMM yyyy)                          | UN UNK 2010  |
| 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)                    | JAN 2010   |
| Start Year (derived)                              | 2010   |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 16:53:15

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|   |  |
|---|--|
| Condition   | MIGRAINE HEADACHES   |
| Start date (dd MMM yyyy)                          | UN UNK 1990  |
| 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)                    | JAN 1990   |
| Start Year (derived)                              | 1990   |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 16:53:15

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|   |  |
|---|--|
| Condition   | POST-MENOPAUSAL  |
| Start date (dd MMM yyyy)                                | UN UNK 2015  |
| 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)                          | JAN 2015   |
| Start Year (derived)                                    | 2015   |
| Stop Month and Year (derived)                           | _____  |
| Stop Year (derived)                                     | _____  |

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 16:53:15

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|   |  |
|---|--|
| Condition   | OSTEOARTHRITIS LEFT KNEE<br>ARTHRITIS                            |
| Start date (dd MMM yyyy)                          | UN UNK 2002  |
| 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)                    | JAN 2002   |
| Start Year (derived)                              | 2002   |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 16:53:15

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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> ) | 01 AUG 2020                          |
| Time of assessment ( <i>00:00-23:59</i> ) | 09:45 (24 HR)                        |
| Vital Signs Date and Time (derived)       | 01 AUG 2020 09:45                    |
| Height ( <i>xxx.x</i> )                   | 169.5 cm                             |
| Weight ( <i>xxx.x</i> )                   | 71.2 kg                              |
| BMI ( <i>xxx.x</i> )                      | 24.78224 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) 15 Feb 2021 16:53:15

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 16:53:15

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Date of assessment (*dd MMM yyyy*) 01 AUG 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

If Partner medically sterile or Other, specify \_\_\_\_\_

If Surgically sterile, date of surgery (*dd MMM yyyy*) \_\_\_\_\_

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN UNK 2015

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 16:53:15

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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 ☒

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**Specify**

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

**No Risk Identified** True

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 16:53:15

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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)  | False |
| <b>Other</b>   | False |
| <b>Specify</b>   |       |



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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 16:53:21

Generated On: 09 Jun 2021 17:26:34

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 01 AUG 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | VISIT1                                  |

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 16:53:21

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

What was the participant's randomization number? 100518

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 16:53:21

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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) 15 Feb 2021 16:53:21

Generated On: 09 Jun 2021 17:26:34

|                                     |  |
|-------------------------------------|--|
| 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 (dd MMM yyyy)    | 01 AUG 2020  |
| Time of assessment (00:00-23:59)    | 09:45 (24 HR)  |
| Vital Signs Date and Time (derived) | 01 AUG 2020 09:45  |
| Temperature (xxx.x)                 | 36.8 C   |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |  |
| Pulse (xxx)                         | 66 beats/min   |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 14 breaths/min   |
| Respiratory Rate units              | BREATHS/MIN  |
| Systolic Blood Pressure (xxx)       | 127 mmHg   |
| Systolic Blood Pressure units       | MMHG   |
| Diastolic Blood Pressure (xxx)      | 79 mmHg  |
| Diastolic Blood Pressure units      | MMHG   |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 16:53:21

Generated On: 09 Jun 2021 17:26:34

|                                     |  |
|-------------------------------------|--|
| Height                              | ND - Not Done  |
| Weight                              | ND - Not Done  |
| Timepoint                           | Pre-Dose <input type="radio"/><br>Post-Dose <input checked="" type="radio"/>                           |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                       |
| Date of assessment (dd MMM yyyy)    | 01 AUG 2020  |
| Time of assessment (00:00-23:59)    | 10:57 (24 HR)  |
| Vital Signs Date and Time (derived) | 01 AUG 2020 10:57  |
| Temperature (xxx.x)                 | 36.8 C   |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |  |
| Pulse (xxx)                         | 87 beats/min   |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 14 breaths/min   |
| Respiratory Rate units              | BREATHS/MIN  |
| Systolic Blood Pressure (xxx)       | 130 mmHg   |
| Systolic Blood Pressure units       | MMHG   |
| Diastolic Blood Pressure (xxx)      | 87 mmHg  |
| Diastolic Blood Pressure units      | MMHG   |

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 16:53:15

Generated On: 09 Jun 2021 17:26:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 16:53:15

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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) 01 AUG 2020

What was the treatment time? (00:00-23:59) 10:25 (24 HR)

Treatment Date and Time (derived) 01 AUG 2020 10:25

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) 15 Feb 2021 16:53:15

Generated On: 09 Jun 2021 17:26:34

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 01 AUG 2020                          |
| Collection time (00:00-23:59)      | 10:10 (24 HR)                        |
| Collection date and time (derived) | 01 AUG 2020 10:10                    |



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 16:53:15

Generated On: 09 Jun 2021 17:26:34

|                               |                           |                                 |                                    |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) |                           |                                 | 01 AUG 2020                        |
| Lab Test                      | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1         | Yes                       | 09:55                           | 01 AUG 2020 09:55                  |
| Nasopharyngeal Swab 2         | No                        |                                 |                                    |

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:53:15

Generated On: 09 Jun 2021 17:26:34

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 17:26:34

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 AUG 2020 10:59

PC Open Date & Time

01 AUG 2020 10:45

PC Close Date & Time

01 AUG 2020 13:15

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

**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 98.7 °F

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

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

|                      |                   |
|----------------------|-------------------|
| PC Time Stamp        | 01 AUG 2020 20:37 |
| PC Open Date & Time  | 01 AUG 2020 14:10 |
| PC Close Date & Time | 02 AUG 2020 11:59 |

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 AUG 2020 12:00

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 AUG 2020 12:35

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 12:02

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 AUG 2020 12:05

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59



US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

06 AUG 2020 12:28

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 13:02

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

01 AUG 2020 10:59

PC Open Date & Time

01 AUG 2020 10:45

PC Close Date & Time

01 AUG 2020 13:15

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

01 AUG 2020 20:38

PC Open Date & Time

01 AUG 2020 14:10

PC Close Date & Time

02 AUG 2020 11:59

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 AUG 2020 12:01

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

03 AUG 2020 12:36

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:26:34

**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

04 AUG 2020 12:02

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

05 AUG 2020 12:05

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59



US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 AUG 2020 12:28

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 13:02

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

**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 ☐

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 01 AUG 2020 11:00 |
| PC Open Date & Time  | 01 AUG 2020 10:45 |
| PC Close Date & Time | 01 AUG 2020 13:15 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

**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 ☐

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 01 AUG 2020 20:38 |
| PC Open Date & Time  | 01 AUG 2020 14:10 |
| PC Close Date & Time | 02 AUG 2020 11:59 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:26:34

**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 ☒

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:26:34

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 02 AUG 2020 12:01 |
| PC Open Date & Time          | 02 AUG 2020 12:00 |
| PC Close Date & Time         | 03 AUG 2020 11:59 |



US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:26:34

**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 ☒

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:26:34

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 03 AUG 2020 12:36 |
| PC Open Date & Time          | 03 AUG 2020 12:00 |
| PC Close Date & Time         | 04 AUG 2020 11:59 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:26:34

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

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:26:34

**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 ☒

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:26:34

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

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 6

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:26:34

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 06 AUG 2020 12:28 |
| PC Open Date & Time          | 06 AUG 2020 12:00 |
| PC Close Date & Time         | 07 AUG 2020 11:59 |



US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:26:34

**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 ☒

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:26:34

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 07 AUG 2020 13:02 |
| PC Open Date & Time          | 07 AUG 2020 12:00 |
| PC Close Date & Time         | 08 AUG 2020 11:59 |

US3402139

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:53:15

Generated On: 09 Jun 2021 17:26:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3402139

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:53:15

Generated On: 09 Jun 2021 17:26:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402139

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:53:15

Generated On: 09 Jun 2021 17:26:34

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 AUG 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3402139

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:53:15

Generated On: 09 Jun 2021 17:26:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402139

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:53:15

Generated On: 09 Jun 2021 17:26:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3402139

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:53:15

Generated On: 09 Jun 2021 17:26:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3402139

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 16:53:21

Generated On: 09 Jun 2021 17:26:34

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 31 AUG 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | VISIT2                                  |

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 16:53:21

Generated On: 09 Jun 2021 17:26:34

|                                     |   |
|-------------------------------------|---|
| Timepoint                           | Pre-Dose <input checked="" type="radio"/> |
|                                     | Post-Dose <input type="radio"/>           |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>      |
|                                     | No <input type="radio"/>                  |
| Date of assessment (dd MMM yyyy)    | 31 AUG 2020                               |
| Time of assessment (00:00-23:59)    | 08:14 (24 HR)                             |
| Vital Signs Date and Time (derived) | 31 AUG 2020 08:14                         |
| Temperature (xxx.x)                 | 36.8 C                                    |
| Route of measurement                | Oral <input checked="" type="radio"/>     |
|                                     | Axillary <input type="radio"/>            |
|                                     | Other <input type="radio"/>               |
| If Other, specify                   |   |
| Pulse (xxx)                         | 63 beats/min                              |
| Pulse units                         | BPM                                       |
| Respiratory Rate (xxx)              | 14 breaths/min                            |
| Respiratory Rate units              | BREATHS/MIN                               |
| Systolic Blood Pressure (xxx)       | 114 mmHg                                  |
| Systolic Blood Pressure units       | MMHG                                      |
| Diastolic Blood Pressure (xxx)      | 60 mmHg                                   |
| Diastolic Blood Pressure units      | MMHG                                      |

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 16:53:21

Generated On: 09 Jun 2021 17:26:34

|                                     |  |
|-------------------------------------|--|
| Timepoint                           | Pre-Dose <input type="radio"/>             |
|                                     | Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>       |
|                                     | No <input type="radio"/>                   |
| Date of assessment (dd MMM yyyy)    | 31 AUG 2020                                |
| Time of assessment (00:00-23:59)    | 09:12 (24 HR)                              |
| Vital Signs Date and Time (derived) | 31 AUG 2020 09:12                          |
| Temperature (xxx.x)                 | 36.8 C                                     |
| Route of measurement                | Oral <input checked="" type="radio"/>      |
|                                     | Axillary <input type="radio"/>             |
|                                     | Other <input type="radio"/>                |
| If Other, specify                   |  |
| Pulse (xxx)                         | 56 beats/min                               |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 14 breaths/min                             |
| Respiratory Rate units              | BREATHS/MIN                                |
| Systolic Blood Pressure (xxx)       | 118 mmHg                                   |
| Systolic Blood Pressure units       | MMHG                                       |
| Diastolic Blood Pressure (xxx)      | 78 mmHg                                    |
| Diastolic Blood Pressure units      | MMHG                                       |

US3402139

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 16:53:21

Generated On: 09 Jun 2021 17:26:34

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

31 AUG 2020

---

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

---

US3402139

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 16:53:21

Generated On: 09 Jun 2021 17:26:34

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) 31 AUG 2020

What was the treatment time? (00:00-23:59) 08:40 (24 HR)

Treatment Date and Time (derived) 31 AUG 2020 08:40

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

US3402139

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 16:53:21

Generated On: 09 Jun 2021 17:26:34

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 31 AUG 2020                          |
| Collection time (00:00-23:59)      | 08:33 (24 HR)                        |
| Collection date and time (derived) | 31 AUG 2020 08:33                    |

US3402139

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 16:53:21

Generated On: 09 Jun 2021 17:26:34

|                               |                           |                                 |                                    |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) |                           |                                 | 31 AUG 2020                        |
| Lab Test                      | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1         | Yes                       | 08:35                           | 31 AUG 2020 08:35                  |
| Nasopharyngeal Swab 2         | No                        |                                 |                                    |

US3402139

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:53:21

Generated On: 09 Jun 2021 17:26:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

**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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 09:11

PC Open Date & Time

31 AUG 2020 09:00

PC Close Date & Time

31 AUG 2020 11:30

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

**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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 13:25

PC Open Date & Time

31 AUG 2020 12:25

PC Close Date & Time

01 SEP 2020 11:59

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:26:34

**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              | 99.2 °F                              |
| Was any <b>MEDICATION TAKEN</b> today for pain or fever? | Yes <input checked="" type="radio"/> |
|  | No <input type="radio"/>             |

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

|   |       |
|---|-------|
| To <b>TREAT</b> pain or fever that has already occurred | True  |
| To <b>PREVENT</b> pain or fever from occurring          | False |

|                      |                   |
|----------------------|-------------------|
| PC Time Stamp        | 01 SEP 2020 16:11 |
| PC Open Date & Time  | 01 SEP 2020 12:00 |
| PC Close Date & Time | 02 SEP 2020 11:59 |

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 13:52

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 12:41

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 12:02

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

05 SEP 2020 12:04

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 20:41

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59



US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 09:12

PC Open Date & Time

31 AUG 2020 09:00

PC Close Date & Time

31 AUG 2020 11:30

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

**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

31 AUG 2020 13:26

PC Open Date & Time

31 AUG 2020 12:25

PC Close Date & Time

01 SEP 2020 11:59

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 16:13

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 13:50

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:26:34

**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

03 SEP 2020 12:39

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 12:02

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 12:04

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 20:41

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59



US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

**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 ☐

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 31 AUG 2020 09:13 |
| PC Open Date & Time  | 31 AUG 2020 09:00 |
| PC Close Date & Time | 31 AUG 2020 11:30 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

**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 ☐

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 31 AUG 2020 13:26 |
| PC Open Date & Time  | 31 AUG 2020 12:25 |
| PC Close Date & Time | 01 SEP 2020 11:59 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:26:34

**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 ☒

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:26:34

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 01 SEP 2020 16:13 |
| PC Open Date & Time          | 01 SEP 2020 12:00 |
| PC Close Date & Time         | 02 SEP 2020 11:59 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:26:34

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:26:34

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 02 SEP 2020 13:50 |
| PC Open Date & Time          | 02 SEP 2020 12:00 |
| PC Close Date & Time         | 03 SEP 2020 11:59 |



US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:26:34

**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 ☒

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:26:34

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 03 SEP 2020 12:40 |
| PC Open Date & Time          | 03 SEP 2020 12:00 |
| PC Close Date & Time         | 04 SEP 2020 11:59 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:26:34

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 ☒

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:26:34

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

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:26:34

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:26:34

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 05 SEP 2020 12:04 |
| PC Open Date & Time          | 05 SEP 2020 12:00 |
| PC Close Date & Time         | 06 SEP 2020 11:59 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:26:34

**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 ☒

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Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:26:34

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 06 SEP 2020 20:42 |
| PC Open Date & Time          | 06 SEP 2020 12:00 |
| PC Close Date & Time         | 07 SEP 2020 11:59 |



US3402139

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:53:15

Generated On: 09 Jun 2021 17:26:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3402139

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:53:15

Generated On: 09 Jun 2021 17:26:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402139

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:53:15

Generated On: 09 Jun 2021 17:26:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3402139

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:53:15

Generated On: 09 Jun 2021 17:26:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402139

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:53:15

Generated On: 09 Jun 2021 17:26:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3402139

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:53:15

Generated On: 09 Jun 2021 17:26:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402139

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 16:53:21

Generated On: 09 Jun 2021 17:26:34

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 25 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  | VISIT3                                  |

US3402139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 16:53:21

Generated On: 09 Jun 2021 17:26:34

|                                     |                                       |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>  |
|                                     | No <input type="radio"/>              |
| Date of assessment (dd MMM yyyy)    | 25 SEP 2020                           |
| Time of assessment (00:00-23:59)    | 13:07 (24 HR)                         |
| Vital Signs Date and Time (derived) | 25 SEP 2020 13:07                     |
| Temperature (xxx.x)                 | 98.8 F                                |
| Route of measurement                | Oral <input checked="" type="radio"/> |
|                                     | Axillary <input type="radio"/>        |
|                                     | Other <input type="radio"/>           |
| If Other, specify                   |                                       |
| Pulse (xxx)                         | 65 beats/min                          |
| Pulse units                         | BPM                                   |
| Respiratory Rate (xxx)              | 12 breaths/min                        |
| Respiratory Rate units              | BREATHS/MIN                           |
| Systolic Blood Pressure (xxx)       | 120 mmHg                              |
| Systolic Blood Pressure units       | MMHG                                  |
| Diastolic Blood Pressure (xxx)      | 73 mmHg                               |
| Diastolic Blood Pressure units      | MMHG                                  |
| Height (derived)                    |                                       |
| Weight (derived)                    |                                       |



US3402139

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 16:53:21

Generated On: 09 Jun 2021 17:26:34

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.*

US3402139

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 16:53:21

Generated On: 09 Jun 2021 17:26:34

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 25 SEP 2020                          |
| Collection time (00:00-23:59)      | 13:13 (24 HR)                        |
| Collection date and time (derived) | 25 SEP 2020 13:13                    |

US3402139

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:53:21

Generated On: 09 Jun 2021 17:26:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | 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   | 02 OCT 2020 10:50:46   |
| Patient Cloud Open Date & Time  | 01 OCT 2020 00:01  |
| Patient Cloud Close Date & Time   | 05 OCT 2020 23:59  |

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

| 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   | 10 OCT 2020 07:32:16   |
| Patient Cloud Open Date & Time  | 08 OCT 2020 00:01  |
| Patient Cloud Close Date & Time   | 12 OCT 2020 23:59  |

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

| TIMEPOINT   | DAY 78   |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input 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   | 18 OCT 2020 07:47:59   |
| Patient Cloud Open Date & Time  | 15 OCT 2020 00:01  |
| Patient Cloud Close Date & Time   | 19 OCT 2020 23:59  |

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

| TIMEPOINT   | DAY 92   |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><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   | 30 OCT 2020 10:04:11   |
| Patient Cloud Open Date & Time  | 29 OCT 2020 00:01  |
| Patient Cloud Close Date & Time   | 02 NOV 2020 23:59  |

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

| TIMEPOINT   | DAY 99   |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input 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   | 07 NOV 2020 07:43:15   |
| Patient Cloud Open Date & Time  | 05 NOV 2020 00:01  |
| Patient Cloud Close Date & Time   | 09 NOV 2020 23:59  |



US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 NOV 2020 16:53:13

Patient Cloud Open Date & Time

12 NOV 2020 00:01

Patient Cloud Close Date & Time

16 NOV 2020 23:59

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

| TIMEPOINT   | DAY 113   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><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 type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq$ 100.4°F/38°C)   | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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

Date and time of submission

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

| 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   | 19 NOV 2020 16:50:59   |
| Patient Cloud Open Date & Time  | 16 NOV 2020 00:01  |
| Patient Cloud Close Date & Time   | 20 NOV 2020 23:59  |

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 NOV 2020 13:26:50

Patient Cloud Open Date & Time

23 NOV 2020 00:01

Patient Cloud Close Date & Time

27 NOV 2020 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

| TIMEPOINT   | DAY 124  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><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   | 04 DEC 2020 14:08:13   |
| Patient Cloud Open Date & Time  | 30 NOV 2020 00:01  |
| Patient Cloud Close Date & Time   | 04 DEC 2020 23:59  |

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

| TIMEPOINT   | DAY 131   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><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 type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 07 DEC 2020 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 11 DEC 2020 23:59 |



US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

| TIMEPOINT   | DAY 138  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input 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 type="radio"/><br>Yes <input checked="" type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Date and time of submission   | 14 DEC 2020 15:37:43   |
| Patient Cloud Open Date & Time  | 14 DEC 2020 00:01  |
| Patient Cloud Close Date & Time   | 18 DEC 2020 23:59  |

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

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21 DEC 2020 00:01

---

[Patient Cloud Close Date & Time](#)

---

25 DEC 2020 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 DEC 2020 12:27:12

Patient Cloud Open Date & Time

28 DEC 2020 00:01

Patient Cloud Close Date & Time

01 JAN 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 JAN 2021 18:55:03

Patient Cloud Open Date & Time

04 JAN 2021 00:01

Patient Cloud Close Date & Time

08 JAN 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | DAY 166  |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><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   | 11 JAN 2021 08:49:09   |
| Patient Cloud Open Date & Time  | 11 JAN 2021 00:01  |
| Patient Cloud Close Date & Time   | 15 JAN 2021 23:59  |

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 JAN 2021 08:28:22

Patient Cloud Open Date & Time

18 JAN 2021 00:01

Patient Cloud Close Date & Time

22 JAN 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 JAN 2021 12:49:15

Patient Cloud Open Date & Time

25 JAN 2021 00:01

Patient Cloud Close Date & Time

29 JAN 2021 23:59



US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 FEB 2021 14:00:51

Patient Cloud Open Date & Time

01 FEB 2021 00:01

Patient Cloud Close Date & Time

05 FEB 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

| TIMEPOINT   | DAY 194  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><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   | 11 FEB 2021 07:10:31   |
| Patient Cloud Open Date & Time  | 08 FEB 2021 00:01  |
| Patient Cloud Close Date & Time   | 12 FEB 2021 23:59  |

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

| TIMEPOINT   | DAY 201  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><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 FEB 2021 10:21:25   |
| Patient Cloud Open Date & Time  | 15 FEB 2021 00:01  |
| Patient Cloud Close Date & Time   | 19 FEB 2021 23:59  |

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 208

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

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

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

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

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

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

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

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 22 FEB 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 26 FEB 2021 23:59 |

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAR 2021 09:32:04

Patient Cloud Open Date & Time

01 MAR 2021 00:01

Patient Cloud Close Date & Time

05 MAR 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 MAR 2021 09:26:04

Patient Cloud Open Date & Time

08 MAR 2021 00:01

Patient Cloud Close Date & Time

12 MAR 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 MAR 2021 08:05:50

Patient Cloud Open Date & Time

15 MAR 2021 00:01

Patient Cloud Close Date & Time

19 MAR 2021 23:59



US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 MAR 2021 08:51:28

Patient Cloud Open Date & Time

22 MAR 2021 00:01

Patient Cloud Close Date & Time

26 MAR 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 MAR 2021 16:36:51

Patient Cloud Open Date & Time

29 MAR 2021 00:01

Patient Cloud Close Date & Time

02 APR 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 APR 2021 10:50:37

Patient Cloud Open Date & Time

05 APR 2021 00:01

Patient Cloud Close Date & Time

09 APR 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 15:22:48

Patient Cloud Open Date & Time

12 APR 2021 00:01

Patient Cloud Close Date & Time

16 APR 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 06:52:11

Patient Cloud Open Date & Time

19 APR 2021 00:01

Patient Cloud Close Date & Time

23 APR 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 271

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 APR 2021 07:51:14

Patient Cloud Open Date & Time

26 APR 2021 00:01

Patient Cloud Close Date & Time

30 APR 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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03 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 MAY 2021 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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10 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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14 MAY 2021 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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17 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 MAY 2021 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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24 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 MAY 2021 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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31 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 JUN 2021 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

14 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

| TIMEPOINT   | DAY 327  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 21 JUN 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 25 JUN 2021 23:59 |

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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28 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 JUL 2021 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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05 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 JUL 2021 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

| TIMEPOINT   | DAY 348  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUL 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

19 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 JUL 2021 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

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

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUL 2021 23:59



US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

| TIMEPOINT   | DAY 369   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="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 type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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02 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 AUG 2021 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

| TIMEPOINT   | DAY 376  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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09 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 AUG 2021 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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16 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 AUG 2021 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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|  |                   |
|--|-------------------|
| <a href="#">Patient Cloud Open Date &amp; Time</a> | 23 AUG 2021 00:01 |
|--|-------------------|

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|   |                   |
|---|-------------------|
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 27 AUG 2021 23:59 |
|---|-------------------|

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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30 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 SEP 2021 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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06 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 SEP 2021 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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13 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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17 SEP 2021 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

20 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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27 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 OCT 2021 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

| TIMEPOINT   | DAY 432   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="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 type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

08 OCT 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

15 OCT 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 18 OCT 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 22 OCT 2021 23:59 |



US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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| <a href="#">Patient Cloud Open Date &amp; Time</a> | 25 OCT 2021 00:01 |
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| <a href="#">Patient Cloud Close Date &amp; Time</a> | 29 OCT 2021 23:59 |
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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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[Patient Cloud Open Date & Time](#)

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08 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 NOV 2021 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

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

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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|  |                   |
|--|-------------------|
| <a href="#">Patient Cloud Open Date &amp; Time</a> | 15 NOV 2021 00:01 |
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| <a href="#">Patient Cloud Close Date &amp; Time</a> | 19 NOV 2021 23:59 |
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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 22 NOV 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 26 NOV 2021 23:59 |

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 29 NOV 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 03 DEC 2021 23:59 |

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 06 DEC 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 10 DEC 2021 23:59 |

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 13 DEC 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 17 DEC 2021 23:59 |



US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 20 DEC 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 24 DEC 2021 23:59 |

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 27 DEC 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 31 DEC 2021 23:59 |

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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03 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 JAN 2022 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59



US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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17 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 JAN 2022 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2022 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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31 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 FEB 2022 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

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

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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07 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 FEB 2022 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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14 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 FEB 2022 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 21 FEB 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 25 FEB 2022 23:59 |

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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28 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 MAR 2022 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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07 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAR 2022 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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14 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAR 2022 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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21 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAR 2022 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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28 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 APR 2022 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 04 APR 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 08 APR 2022 23:59 |



US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 11 APR 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 15 APR 2022 23:59 |

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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18 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 APR 2022 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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|  |                   |
|--|-------------------|
| <a href="#">Patient Cloud Open Date &amp; Time</a> | 25 APR 2022 00:01 |
|--|-------------------|

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|   |                   |
|---|-------------------|
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 29 APR 2022 23:59 |
|---|-------------------|

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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02 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 MAY 2022 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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09 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 MAY 2022 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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16 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAY 2022 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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23 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 MAY 2022 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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30 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 JUN 2022 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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06 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 JUN 2022 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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13 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 JUN 2022 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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20 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 JUN 2022 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

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

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

27 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

01 JUL 2022 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

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

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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04 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 JUL 2022 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

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

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 11 JUL 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 15 JUL 2022 23:59 |

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 18 JUL 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 22 JUL 2022 23:59 |

US3402139

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Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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|  |                   |
|--|-------------------|
| <a href="#">Patient Cloud Open Date &amp; Time</a> | 25 JUL 2022 00:01 |
|--|-------------------|

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|   |                   |
|---|-------------------|
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 29 JUL 2022 23:59 |
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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 733

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

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

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

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

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

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

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

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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01 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 AUG 2022 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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08 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 AUG 2022 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

---

Date and time of submission

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|  |                   |
|--|-------------------|
| <a href="#">Patient Cloud Open Date &amp; Time</a> | 15 AUG 2022 00:01 |
|--|-------------------|

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|   |                   |
|---|-------------------|
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 19 AUG 2022 23:59 |
|---|-------------------|

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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22 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 AUG 2022 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2022 23:59

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 768

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

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

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

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

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

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

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

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 05 SEP 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 09 SEP 2022 23:59 |

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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12 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 SEP 2022 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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19 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 SEP 2022 23:59

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US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 26 SEP 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 30 SEP 2022 23:59 |

US3402139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

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

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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03 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 OCT 2022 23:59

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**US3402139**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 09 Jun 2021 17:26:34**

| Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other? | Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache? | Date & Time of Submission |
|---|--|---------------------------|
| No  |  | 01 MAR 2021 09:32:20      |

US3402139

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 22:16:31

Generated On: 09 Jun 2021 17:26:34

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3402139

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 22:16:31

Generated On: 09 Jun 2021 17:26:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402139

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 01:45:46

Generated On: 09 Jun 2021 17:26:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3402139

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 01:45:46

Generated On: 09 Jun 2021 17:26:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402139

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 01:45:46

Generated On: 09 Jun 2021 17:26:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3402139

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 01:45:46

Generated On: 09 Jun 2021 17:26:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402139

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 01:45:46

Generated On: 09 Jun 2021 17:26:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3402139

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 01:45:46

Generated On: 09 Jun 2021 17:26:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402139

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 01:45:46

Generated On: 09 Jun 2021 17:26:34

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

|                          |             |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 22 FEB 2021 |
|--------------------------|-------------|

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

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

US3402139

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 01:45:46

Generated On: 09 Jun 2021 17:26:34

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) \_\_\_\_\_

US3402139

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 01:45:46

Generated On: 09 Jun 2021 17:26:34

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.*



US3402139

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 01:45:46

Generated On: 09 Jun 2021 17:26:34

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 FEB 2021

Collection time (00:00-23:59)

08:31 (24 HR)

Collection date and time (derived)

22 FEB 2021 08:31

US3402139

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 01:45:46

Generated On: 09 Jun 2021 17:26:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402139

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 01:45:46

Generated On: 09 Jun 2021 17:26:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3402139

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 01:45:46

Generated On: 09 Jun 2021 17:26:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3402139**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

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*

**US3402139**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:26:34**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3402139

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:26:34

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

**US3402139**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 09 Jun 2021 17:26:34**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---



US3402139

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

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 01:45:45

Generated On: 09 Jun 2021 17:26:34

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

|                          |             |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 21 JAN 2021 |
|--------------------------|-------------|

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

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

US3402139

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

Form: Unblinding

Data signed: (b) (4) 26 Apr 2021 01:45:45

Generated On: 09 Jun 2021 17:26:34

Date of updated informed consent (*dd MMM yyyy*) 06 JAN 2021

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

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*) 21 JAN 2021

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 \_\_\_\_\_

US3402139

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 01:45:45

Generated On: 09 Jun 2021 17:26:34

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 21 JAN 2021                          |
| Collection time (00:00-23:59)      | 21:33 (24 HR)                        |
| Collection date and time (derived) | 21 JAN 2021 21:33                    |

US3402139

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Apr 2021 01:45:45

Generated On: 09 Jun 2021 17:26:34

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 21 JAN 2021                          |
| Collection time (00:00 - 23:59)    | 07:26                                |
| Collection Date and Time (derived) | 21 JAN 2021 07:26                    |

US3402139

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 14 Mar 2021 14:35:41

Generated On: 09 Jun 2021 17:26:34

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3402139

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 14 Mar 2021 14:35:41

Generated On: 09 Jun 2021 17:26:34

|  |  |
|--|--|
| AEID   | USA-US059-2020-MRNA-1273-P30<br>1000014  |
| Adverse event  | WORSENING LEFT KNEE<br>OSTEOARTHRITIS  |
| Was this a medically-attended AE?                              | Yes <input checked="" type="radio"/><br>No <input type="radio"/>   |
| Was this a Solicited Adverse Reaction?                         | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Is this event a confirmed diagnosis of Symptomatic Covid-19?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Start date (dd MMM yyyy)                                       | 09 AUG 2020  |
| Start time (00:00-23:59)                                       |  |
| AE start date and time (derived)                               |  |
| Ongoing?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| If not Ongoing, end date (dd MMM yyyy)                         | 14 OCT 2020  |
| End time (00:00-23:59)   |  |
| AE End Date and Time (derived)                                 |  |
| Severity   | Grade 1/Mild <input type="radio"/><br>Grade 2/Moderate <input checked="" type="radio"/><br>Grade 3/Severe <input type="radio"/><br>Grade 4 <input type="radio"/> |
| Is the adverse event serious?                                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/>   |
| AE is serious due To (check all that apply)                    |  |
| Death  | False  |
| Life threatening   | False  |
| Requires inpatient or prolongation of existing Hospitalization | True   |
| Hospital Admission Date (dd MMM yyyy)                          | 12 OCT 2020  |
| Hospital Discharge Date (dd MMM yyyy)                          | 14 OCT 2020  |
| Admitted to ICU?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/><br>Unknown <input type="radio"/>  |
| PRODUCTION RELEASE (v12.003<br>EAB) (1725)                     | 325 of 2266  |

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 14 Mar 2021 14:35:41

Generated On: 09 Jun 2021 17:26:34

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

US3402139

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 14 Mar 2021 14:35:41

Generated On: 09 Jun 2021 17:26:34

---

SUBJECT WAS ADMITTED  
12OCT2020 FOR A LEFT KNEE  
REPLACEMENT. SUBJECT WAS  
DISCHARGED 14OCT2020.  
SUBJECT DID HAVE COVID 19  
TESTING DONE WHICH WAS  
NEGATIVE. SUBJECT DID HAVE  
COMPLETE BLOOD COUNT  
WHICH SHOWED THAT THE  
HEMAGLOBIN WAS 10.8 ON  
13OCT2020, AND 11.1 14OCT2020  
BOTH OF WHICH WERE LOW  
THE NORMAL RANGE IS  
12.0-16.0.

---

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

---



US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 08 Apr 2021 23:27:02

Generated On: 09 Jun 2021 17:26:34

---

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

Yes ☒

No ☐

---

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

---

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 15 Apr 2021 00:02:44

Generated On: 09 Jun 2021 17:26:34

Name of Medication LEVOCETIRIZINE

Prophylaxis Yes ☐  
No ☒

Indication ENVIRONMENTAL ALLERGIES

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 15 Apr 2021 00:02:44

Generated On: 09 Jun 2021 17:26:34

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intramuscular            | <input type="checkbox"/>         |
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | UN MAY 2019              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   | 1                        |                                  |
| Interval Dosage Unit Number (derived)              | 1                        |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 15 Apr 2021 00:02:44

Generated On: 09 Jun 2021 17:26:34

Name of Medication RIZATRIPTAN BENZOATE

Prophylaxis Yes ☐  
No ☒

Indication MIGRAINE HEADACHES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 15 Apr 2021 00:02:44

Generated On: 09 Jun 2021 17:26:34

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intramuscular            | <input type="checkbox"/>         |
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | UN UNK 2007              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) _____             |                          |                                  |
| Interval Dosage Unit Number (derived) _____        |                          |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input type="radio"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 15 Apr 2021 00:02:44

Generated On: 09 Jun 2021 17:26:34

Name of Medication TURMERIC CURCUMIN

Prophylaxis Yes ☒  
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 15 Apr 2021 00:02:44

Generated On: 09 Jun 2021 17:26:34

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 15 Apr 2021 00:02:44

Generated On: 09 Jun 2021 17:26:34

Name of Medication MAGNESIUM OXIDE

Prophylaxis Yes ☒  
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 15 Apr 2021 00:02:44

Generated On: 09 Jun 2021 17:26:34

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 15 Apr 2021 00:02:44

Generated On: 09 Jun 2021 17:26:34

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication MILD PAIN AT INJECTION SITE  
AND BODY ACHES

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 15 Apr 2021 00:02:44

Generated On: 09 Jun 2021 17:26:34

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Intraocular              | <input type="checkbox"/>            |
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input type="checkbox"/>            |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           |                          | 01 SEP 2020                         |
| Start date completely unknown                      |                          | False                               |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 02 SEP 2020                         |
| Was this medication taken for solicited event?     | Yes                      | <input checked="" type="checkbox"/> |
|  | No                       | <input type="checkbox"/>            |
| Separate Dosage Number (derived) _____             |                          |                                     |
| Interval Dosage Unit Number (derived) _____        |                          |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input type="checkbox"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 15 Apr 2021 00:02:44

Generated On: 09 Jun 2021 17:26:34

Name of Medication AMBIEN

Prophylaxis Yes ☐  
No ☒

Indication WORSENING LEFT KNEE  
ARTHRITIS

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 15 Apr 2021 00:02:44

Generated On: 09 Jun 2021 17:26:34

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Intraocular              | <input type="checkbox"/>            |
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input type="checkbox"/>            |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify   |                          |                                     |
| Start date (dd MMM yyyy)                       | 12 OCT 2020              |                                     |
| Start date completely unknown                  | False                    |                                     |
| Ongoing?                                       | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)         |                          | 14 OCT 2020                         |
| Was this medication taken for solicited event? | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)               |                          |                                     |
| Interval Dosage Unit Number (derived)          |                          |                                     |
| Interval Dosage Definition (derived)           | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input type="checkbox"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 15 Apr 2021 00:02:44

Generated On: 09 Jun 2021 17:26:34

Name of Medication ATARAX - HYDROXYZINE  
HYDROCHLORIDE

Prophylaxis Yes ☐  
No ☒

Indication WORSENING LEFT KNEE  
ARTHRITIS

Dose per administration 50

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

EVERY THREE HOUR AS  
NEEDED

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

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|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Transdermal              | <input type="checkbox"/>            |
|  | Intraocular              | <input type="checkbox"/>            |
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input type="checkbox"/>            |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           | 12 OCT 2020              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 14 OCT 2020                         |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____             |                          |                                     |
| Interval Dosage Unit Number (derived) _____        |                          |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input type="checkbox"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 15 Apr 2021 00:02:44

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Name of Medication CELEBREX

Prophylaxis Yes ☐  
No ☒

Indication WORSENING LEFT KNEE  
ARTHRITIS

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

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|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Intraocular              | <input type="checkbox"/>            |
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input type="checkbox"/>            |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify   |                          |                                     |
| Start date (dd MMM yyyy)                       | 12 OCT 2020              |                                     |
| Start date completely unknown                  | False                    |                                     |
| Ongoing?                                       | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)         | 14 OCT 2020              |                                     |
| Was this medication taken for solicited event? | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)               | 2                        |                                     |
| Interval Dosage Unit Number (derived)          | 1                        |                                     |
| Interval Dosage Definition (derived)           | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input checked="" type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 15 Apr 2021 00:02:44

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Name of Medication DULCOLAX

Prophylaxis Yes ☐  
No ☒

Indication WORSENING LEFT KNEE  
ARTHRITIS

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

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|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Intraocular              | <input type="checkbox"/>            |
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input type="checkbox"/>            |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           |                          | 12 OCT 2020                         |
| Start date completely unknown                      |                          | False                               |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 14 OCT 2020                         |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____             |                          |                                     |
| Interval Dosage Unit Number (derived) _____        |                          |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input type="checkbox"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 15 Apr 2021 00:02:44

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Name of Medication ECOTRIN

Prophylaxis Yes ☐  
No ☒

Indication WORSENING LEFT KNEE  
ARTHRITIS

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

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|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Intraocular              | <input type="checkbox"/>            |
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input type="checkbox"/>            |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify   |                          |                                     |
| Start date (dd MMM yyyy)                       | 12 OCT 2020              |                                     |
| Start date completely unknown                  | False                    |                                     |
| Ongoing?                                       | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)         | 14 OCT 2020              |                                     |
| Was this medication taken for solicited event? | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)               | 1                        |                                     |
| Interval Dosage Unit Number (derived)          | 1                        |                                     |
| Interval Dosage Definition (derived)           | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input checked="" type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 15 Apr 2021 00:02:44

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Name of Medication FAMOTIDINE

Prophylaxis Yes ☐  
No ☒

Indication WORSENING LEFT KNEE  
ARTHRITIS

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 15 Apr 2021 00:02:44

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|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Intraocular              | <input type="checkbox"/>            |
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input type="checkbox"/>            |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify   |                          |                                     |
| Start date (dd MMM yyyy)                       | 12 OCT 2020              |                                     |
| Start date completely unknown                  | False                    |                                     |
| Ongoing?                                       | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)         |                          | 14 OCT 2020                         |
| Was this medication taken for solicited event? | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)               | 1                        |                                     |
| Interval Dosage Unit Number (derived)          | 1                        |                                     |
| Interval Dosage Definition (derived)           | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input checked="" type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 15 Apr 2021 00:02:44

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Name of Medication FAMOTIDINE

Prophylaxis Yes ☐  
No ☒

Indication WORSENING LEFT KNEE  
ARTHRITIS

Dose per administration 20/2

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

If dose unit is Other, specify MG/ML

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

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|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intraocular              | <input type="radio"/>            |
|  | Intramuscular            | <input type="radio"/>            |
|  | Respiratory (Inhalation) | <input type="radio"/>            |
|  | Intralesional            | <input type="radio"/>            |
|  | Intraperitoneal          | <input type="radio"/>            |
|  | Nasal                    | <input type="radio"/>            |
|  | Vaginal                  | <input type="radio"/>            |
|  | Rectal                   | <input type="radio"/>            |
|  | Intravenous              | <input checked="" type="radio"/> |
|  | Intravenous Bolus        | <input type="radio"/>            |
|  | Intravenous Drip         | <input type="radio"/>            |
|  | Other                    | <input type="radio"/>            |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           |                          | 12 OCT 2020                      |
| Start date completely unknown                      |                          | False                            |
| Ongoing?   | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 14 OCT 2020                      |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) _____             |                          |                                  |
| Interval Dosage Unit Number (derived) _____        |                          |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input type="radio"/>            |

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Form: Prior/Concomitant Medication and Vaccination (13)

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Name of Medication FENTANYL

Prophylaxis Yes ☐  
No ☒

Indication WORSENING LEFT KNEE  
ARTHRITIS

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Form: Prior/Concomitant Medication and Vaccination (13)

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|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Intraocular              | <input type="checkbox"/>            |
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input checked="" type="checkbox"/> |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           |                          | 12 OCT 2020                         |
| Start date completely unknown                      |                          | False                               |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 14 OCT 2020                         |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____             |                          |                                     |
| Interval Dosage Unit Number (derived) _____        |                          |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input type="checkbox"/>            |

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Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 15 Apr 2021 00:02:44

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Name of Medication FERROUS SULFATE

Prophylaxis Yes ☐  
No ☒

Indication WORSENING LEFT KNEE  
ARTHRITIS

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

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|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Intraocular              | <input type="checkbox"/>            |
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input type="checkbox"/>            |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify   |                          |                                     |
| Start date (dd MMM yyyy)                       | 12 OCT 2020              |                                     |
| Start date completely unknown                  | False                    |                                     |
| Ongoing?                                       | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)         | 14 OCT 2020              |                                     |
| Was this medication taken for solicited event? | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)               | 1                        |                                     |
| Interval Dosage Unit Number (derived)          | 1                        |                                     |
| Interval Dosage Definition (derived)           | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input checked="" type="checkbox"/> |

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Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 15 Apr 2021 00:02:44

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Name of Medication FLEET ENEMA

Prophylaxis Yes ☐  
No ☒

Indication WORSENING LEFT KNEE  
ARTHRITIS

Dose per administration 1

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

If dose unit is Other, specify BOTTLE

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intraocular              | <input type="radio"/>            |
|  | Intramuscular            | <input type="radio"/>            |
|  | Respiratory (Inhalation) | <input type="radio"/>            |
|  | Intralesional            | <input type="radio"/>            |
|  | Intraperitoneal          | <input type="radio"/>            |
|  | Nasal                    | <input type="radio"/>            |
|  | Vaginal                  | <input type="radio"/>            |
|  | Rectal                   | <input checked="" type="radio"/> |
|  | Intravenous              | <input type="radio"/>            |
|  | Intravenous Bolus        | <input type="radio"/>            |
|  | Intravenous Drip         | <input type="radio"/>            |
|  | Other                    | <input type="radio"/>            |
| If route of administration is Other, specify   |                          |                                  |
| Start date (dd MMM yyyy)                       | 12 OCT 2020              |                                  |
| Start date completely unknown                  | False                    |                                  |
| Ongoing?                                       | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy)         |                          | 14 OCT 2020                      |
| Was this medication taken for solicited event? | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)               |                          |                                  |
| Interval Dosage Unit Number (derived)          |                          |                                  |
| Interval Dosage Definition (derived)           | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input type="radio"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 15 Apr 2021 00:02:44

Generated On: 09 Jun 2021 17:26:34

Name of Medication GABAPENTIN

Prophylaxis Yes ☐  
No ☒

Indication WORSENING LEFT KNEE  
ARTHRITIS

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 15 Apr 2021 00:02:44

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|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Intraocular              | <input type="checkbox"/>            |
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input type="checkbox"/>            |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify   |                          |                                     |
| Start date (dd MMM yyyy)                       | 12 OCT 2020              |                                     |
| Start date completely unknown                  | False                    |                                     |
| Ongoing?                                       | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)         | 14 OCT 2020              |                                     |
| Was this medication taken for solicited event? | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)               | 2                        |                                     |
| Interval Dosage Unit Number (derived)          | 1                        |                                     |
| Interval Dosage Definition (derived)           | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input checked="" type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 15 Apr 2021 00:02:44

Generated On: 09 Jun 2021 17:26:34

Name of Medication LACTATED RINGERS

Prophylaxis Yes ☐  
No ☒

Indication WORSENING LEFT KNEE  
ARTHRITIS

Dose per administration 1000

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

CONTINUOUS

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 15 Apr 2021 00:02:44

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|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intraocular              | <input type="radio"/>            |
|  | Intramuscular            | <input type="radio"/>            |
|  | Respiratory (Inhalation) | <input type="radio"/>            |
|  | Intralesional            | <input type="radio"/>            |
|  | Intraperitoneal          | <input type="radio"/>            |
|  | Nasal                    | <input type="radio"/>            |
|  | Vaginal                  | <input type="radio"/>            |
|  | Rectal                   | <input type="radio"/>            |
|  | Intravenous              | <input checked="" type="radio"/> |
|  | Intravenous Bolus        | <input type="radio"/>            |
|  | Intravenous Drip         | <input type="radio"/>            |
|  | Other                    | <input type="radio"/>            |
| <hr/>  |                          |                                  |
| If route of administration is Other, specify   |                          |                                  |
| <hr/>  |                          |                                  |
| Start date (dd MMM yyyy)                       | 12 OCT 2020              |                                  |
| Start date completely unknown                  | False                    |                                  |
| Ongoing?                                       | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| <hr/>  |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy)         | 14 OCT 2020              |                                  |
| Was this medication taken for solicited event? | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| <hr/>  |                          |                                  |
| Separate Dosage Number (derived)               | <hr/>                    |                                  |
| Interval Dosage Unit Number (derived)          | <hr/>                    |                                  |
| Interval Dosage Definition (derived)           | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input type="radio"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 15 Apr 2021 00:02:44

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Name of Medication LOVENOX

Prophylaxis Yes ☐  
No ☒

Indication WORSENING LEFT KNEE  
ARTHRITIS

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☒  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 15 Apr 2021 00:02:44

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|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Intraocular              | <input type="checkbox"/>            |
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input type="checkbox"/>            |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify   |                          |                                     |
| Start date (dd MMM yyyy)                       | 12 OCT 2020              |                                     |
| Start date completely unknown                  | False                    |                                     |
| Ongoing?                                       | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)         | 14 OCT 2020              |                                     |
| Was this medication taken for solicited event? | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)               | 1                        |                                     |
| Interval Dosage Unit Number (derived)          | 1                        |                                     |
| Interval Dosage Definition (derived)           | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input checked="" type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 15 Apr 2021 00:02:44

Generated On: 09 Jun 2021 17:26:34

Name of Medication MILK OF MAGNESIA

Prophylaxis Yes ☐  
No ☒

Indication WORSENING LEFT KNEE  
ARTHRITIS

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 15 Apr 2021 00:02:44

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|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Intraocular              | <input type="checkbox"/>            |
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input type="checkbox"/>            |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           |                          | 12 OCT 2020                         |
| Start date completely unknown                      |                          | False                               |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 14 OCT 2020                         |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____             |                          |                                     |
| Interval Dosage Unit Number (derived) _____        |                          |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input type="checkbox"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 15 Apr 2021 00:02:44

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Name of Medication MORPHINE

Prophylaxis Yes ☐  
No ☒

Indication WORSENING LEFT KNEE  
ARTHRITIS

Dose per administration 6

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

EVERY 3 HOURS AS NEEDED

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

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|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intraocular              | <input type="radio"/>            |
|  | Intramuscular            | <input checked="" type="radio"/> |
|  | Respiratory (Inhalation) | <input type="radio"/>            |
|  | Intralesional            | <input type="radio"/>            |
|  | Intraperitoneal          | <input type="radio"/>            |
|  | Nasal                    | <input type="radio"/>            |
|  | Vaginal                  | <input type="radio"/>            |
|  | Rectal                   | <input type="radio"/>            |
|  | Intravenous              | <input type="radio"/>            |
|  | Intravenous Bolus        | <input type="radio"/>            |
|  | Intravenous Drip         | <input type="radio"/>            |
|  | Other                    | <input type="radio"/>            |
| If route of administration is Other, specify   |                          |                                  |
| Start date (dd MMM yyyy)                       | 12 OCT 2020              |                                  |
| Start date completely unknown                  | False                    |                                  |
| Ongoing?                                       | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy)         | 14 OCT 2020              |                                  |
| Was this medication taken for solicited event? | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)               |                          |                                  |
| Interval Dosage Unit Number (derived)          |                          |                                  |
| Interval Dosage Definition (derived)           | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input type="radio"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 15 Apr 2021 00:02:44

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Name of Medication OXYCODONE

Prophylaxis Yes ☐  
No ☒

Indication WORSENING LEFT KNEE  
ARTHRITIS

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 15 Apr 2021 00:02:44

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|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Intraocular              | <input type="checkbox"/>            |
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input type="checkbox"/>            |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           |                          | 12 OCT 2020                         |
| Start date completely unknown                      |                          | False                               |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 14 OCT 2020                         |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____             |                          |                                     |
| Interval Dosage Unit Number (derived) _____        |                          |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input type="checkbox"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 15 Apr 2021 00:02:44

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Name of Medication HYDROCODONE/ACETAMINOP  
HEN

Prophylaxis Yes ☐  
No ☒

Indication LEFT KNEE REPLACEMENT  
(ARTHROPLASTY)

Dose per administration 5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

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|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Intraocular              | <input type="checkbox"/>            |
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input type="checkbox"/>            |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           |                          | 12 OCT 2020                         |
| Start date completely unknown                      |                          | False                               |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 22 OCT 2020                         |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____             |                          |                                     |
| Interval Dosage Unit Number (derived) _____        |                          |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input type="checkbox"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 15 Apr 2021 00:02:44

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Name of Medication AMOXICILLIN/CLAVULANIC  
ACID

Prophylaxis Yes ☐  
No ☒

Indication LEFT KNEE REPLACEMENT  
(ARTHOPLASTY)

Dose per administration 125/875

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Form: Prior/Concomitant Medication and Vaccination (23)

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|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Intraocular              | <input type="checkbox"/>            |
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input type="checkbox"/>            |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify   |                          |                                     |
| Start date (dd MMM yyyy)                       | 12 OCT 2020              |                                     |
| Start date completely unknown                  | False                    |                                     |
| Ongoing?                                       | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)         | 22 OCT 2020              |                                     |
| Was this medication taken for solicited event? | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)               | 1                        |                                     |
| Interval Dosage Unit Number (derived)          | 1                        |                                     |
| Interval Dosage Definition (derived)           | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input checked="" type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 15 Apr 2021 00:02:44

Generated On: 09 Jun 2021 17:26:34

Name of Medication MELOXICAM

Prophylaxis Yes ☐  
No ☒

Indication LEFT KNEE ARTHRITIS

Dose per administration 7.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 15 Apr 2021 00:02:44

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|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | 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)                           | 22 MAR 2021              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   | _____                    |                                  |
| Interval Dosage Unit Number (derived)              | _____                    |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input type="radio"/>            |

US3402139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 23:27:02

Generated On: 09 Jun 2021 17:26:34

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3402139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 08 Apr 2021 23:27:02

Generated On: 09 Jun 2021 17:26:34

| Procedure/Surgery date (dd MMM<br>yyyy) | Procedure/Surgery     | Indication    | If indication is Other, specify |
|---|-----------------------|---------------|---------------------------------|
| 12 OCT 2020                             | LEFT KNEE REPLACEMENT | Adverse Event |                                 |
| 13 OCT 2020                             | COMPLETE BLOOD COUNT  | Adverse Event |                                 |
| 14 OCT 2020                             | COMPLETE BLOOD COUNT  | Adverse Event |                                 |

US3402139

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:26:34

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

US3402139

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:26:34

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

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 01:45:46

Generated On: 09 Jun 2021 17:26:34

|  |  |
|--|--|
| SAEID  | USA-US059-2020-MRNA-1273-P301000014                              |
| Serious  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/><br>No <input 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                                      | FRANK  |
| Investigator's Last Name                                       | EDER   |
| Site Address: Street   | 1290 UPPER FRONT STREET  |
| Site Address: City   | BINGHAMTON   |
| Site Address: State  | NY   |
| Site Address: Postal Code                                      | 13901  |
| Investigator Country   | US   |
| E2B Transmit Flag (Derived/Hidden)                             | 6  |

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 01:45:46

Generated On: 09 Jun 2021 17:26:34

|   |  |
|---|--|
| SAEID   | USA-US059-2020-MRNA-1273-P301000014                              |
| Serious   | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization  | Yes <input checked="" type="radio"/><br>No <input 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   | FRANK  |
| Investigator's Last Name  | EDER   |
| Site Address: Street  | 1290 UPPER FRONT STREET  |
| Site Address: City  | BINGHAMTON   |
| Site Address: State   | NY   |
| Site Address: Postal Code   | 13901  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 6  |
| Date of submission (Pre-filled from custom function)  | 27/OCT/2020 10:25  |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True   |

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 01:45:46

Generated On: 09 Jun 2021 17:26:34

|   |  |
|---|--|
| SAEID   | USA-US059-2020-MRNA-1273-P301000014                              |
| Serious   | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization  | Yes <input checked="" type="radio"/><br>No <input 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   | FRANK  |
| Investigator's Last Name  | EDER   |
| Site Address: Street  | 1290 UPPER FRONT STREET  |
| Site Address: City  | BINGHAMTON   |
| Site Address: State   | NY   |
| Site Address: Postal Code   | 13901  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 6  |
| Date of submission (Pre-filled from custom function)  | 09/NOV/2020 14:27  |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True   |



US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 01:45:46

Generated On: 09 Jun 2021 17:26:34

|   |  |
|---|--|
| SAEID   | USA-US059-2020-MRNA-1273-P301000014                              |
| Serious   | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization  | Yes <input checked="" type="radio"/><br>No <input 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   | FRANK  |
| Investigator's Last Name  | EDER   |
| Site Address: Street  | 1290 UPPER FRONT STREET  |
| Site Address: City  | BINGHAMTON   |
| Site Address: State   | NY   |
| Site Address: Postal Code   | 13901  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 6  |
| Date of submission (Pre-filled from custom function)  | 18/NOV/2020 09:45  |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True   |

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Apr 2021 01:45:46

Generated On: 09 Jun 2021 17:26:34

|   |  |
|---|--|
| SAEID   | USA-US059-2020-MRNA-1273-P301000014                              |
| Serious   | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization  | Yes <input checked="" type="radio"/><br>No <input 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   | FRANK  |
| Investigator's Last Name  | EDER   |
| Site Address: Street  | 1290 UPPER FRONT STREET  |
| Site Address: City  | BINGHAMTON   |
| Site Address: State   | NY   |
| Site Address: Postal Code   | 13901  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 6  |
| Date of submission (Pre-filled from custom function)  | 24/NOV/2020 08:43  |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True   |

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form (5)

Data signed: (b) (4) 26 Apr 2021 01:45:46

Generated On: 09 Jun 2021 17:26:34

|   |  |
|---|--|
| SAEID   | USA-US059-2020-MRNA-1273-P301000014                              |
| Serious   | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization  | Yes <input checked="" type="radio"/><br>No <input 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   | FRANK  |
| Investigator's Last Name  | EDER   |
| Site Address: Street  | 1290 UPPER FRONT STREET  |
| Site Address: City  | BINGHAMTON   |
| Site Address: State   | NY   |
| Site Address: Postal Code   | 13901  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 6  |
| Date of submission (Pre-filled from custom function)  | 02/DEC/2020 11:51  |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True   |

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form (6)

Data signed: (b) (4) 26 Apr 2021 01:45:46

Generated On: 09 Jun 2021 17:26:34

|   |  |
|---|--|
| SAEID   | USA-US059-2020-MRNA-1273-P301000014                              |
| Serious   | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization  | Yes <input checked="" type="radio"/><br>No <input 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   | FRANK  |
| Investigator's Last Name  | EDER   |
| Site Address: Street  | 1290 UPPER FRONT STREET  |
| Site Address: City  | BINGHAMTON   |
| Site Address: State   | NY   |
| Site Address: Postal Code   | 13901  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 6  |
| Date of submission (Pre-filled from custom function)  | 17/DEC/2020 14:09  |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True   |

Audit

US3402139 (Prod: Meridian Clinical Research, LLC)

**US3402139**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 17:26:34**

[Participant ID](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| User signature succeeded. | Frank Eder (b) (4)                          | 26 Apr 2021 01:45:47 |
| User entered 'US3402139'  | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 01 Aug 2020 13:54:06 |

**US3402139**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:26:34**

[Was this visit performed?](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:16 |
| User entered 'Yes (Y)'    | (b) (4)              | 01 Aug 2020 16:20:18 |
|                           | Tarin Gordon (b) (4) |                      |
|                           | (b) (4)              |                      |

**US3402139**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 28 Apr 2021 09:48:32 |
| User signature succeeded.  | Frank Eder (b) (4)                          | 15 Feb 2021 16:53:16 |
| User entered '01 AUG 2020' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 01 Aug 2020 13:54:07 |



US3402139

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:26:34

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

| Audit                          | User                                       | Time (GMT)           |
|--------------------------------|--|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                           | 28 Apr 2021 09:48:32 |
| User signature succeeded.      | Frank Eder (b) (4)                         | 15 Feb 2021 16:53:16 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:20:18 |

**US3402139**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:26:34**

[Folder OID](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 09:48:32 |
| User entered 'SCRN' | System           | 01 Aug 2020 16:20:18 |

**US3402139**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 28 Apr 2021 09:48:32 |
| User signature succeeded.  | Frank Eder (b) (4)                          | 15 Feb 2021 16:53:16 |
| User entered (b) (6) 1965' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 01 Aug 2020 13:54:08 |

**US3402139**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:26:34**

[Age](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered '55'         | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:20:34 |

**US3402139**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:26:34**

[Age Units](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 28 Apr 2021 09:48:32 |
| User entered 'YEARS' | System           | 01 Aug 2020 16:20:34 |

**US3402139**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:26:34**

[Age \(Derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 09:48:32 |
| User entered '55' | System           | 01 Aug 2020 14:28:53 |

US3402139

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:34

[Sex](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered 'Female (F)' | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:20:34 |

**US3402139**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:26:34**

[Ethnicity](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded.                                      | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:20:34 |



**US3402139**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:26:34**

[White](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered 'I'          | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:20:34 |

**US3402139**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:26:34**

[Black](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered '0'          | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:20:34 |

**US3402139**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:26:34**

[Asian](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered '0'          | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:20:34 |

**US3402139**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:26:34**

[American Indian or Alaska Native](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered '0'          | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:20:34 |

**US3402139**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:26:34**

[Native Hawaiian or other Pacific Islander](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered '0'          | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:20:34 |

**US3402139**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:26:34**

[Other](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered '0'          | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:20:34 |

**US3402139**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:26:34**

[If race is Other, specify](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:16 |
| User entered empty.       | (b) (4)              |                      |
|                           | Tarin Gordon (b) (4) | 01 Aug 2020 16:20:34 |
|                           | (b) (4)              |                      |

**US3402139**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:26:34**

[Unknown](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered '0'          | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:20:34 |



**US3402139**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:26:34**

[Not reported](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered '0'          | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:20:34 |

US3402139

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:26:34

Date of Informed Consent (*dd MMM yyyy*)

| Audit   | User               | Time (GMT)           |
|---|--------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)   | 28 Apr 2021 09:48:32 |
| User signature succeeded.                                     | Frank Eder (b) (4) | 15 Feb 2021 16:53:16 |
| User entered '01 Aug 2020' reason for change: New Information | (b) (4)            | 11 Nov 2020 12:17:46 |
| User entered '1 Aug 2020'                                     | Traci Hull (b) (4) | 01 Aug 2020 14:28:53 |
|   | (b) (4)            |                      |

**US3402139**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 09:48:32 |
| User entered 'Aug 2020' | System           | 01 Aug 2020 14:28:53 |

**US3402139**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 09:48:32 |
| User entered '2020' | System           | 01 Aug 2020 14:28:53 |

**US3402139**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:26:34**

[Protocol Version](#)

| Audit                          | User                                       | Time (GMT)           |
|--------------------------------|--|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                           | 28 Apr 2021 09:48:32 |
| User signature succeeded.      | Frank Eder (b) (4)                         | 15 Feb 2021 16:53:16 |
| User entered 'Amendment 1 (1)' | (b) (4)<br>Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 14:28:53 |

**US3402139**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:16 |
| User entered 'Yes (Y)'    | (b) (4)              | 01 Aug 2020 14:28:53 |
|                           | Tarin Gordon (b) (4) |                      |
|                           | (b) (4)              |                      |

**US3402139**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered empty.       | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 14:28:53 |

**US3402139**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:26:34**

If reason for screen fail is Other, specify

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered empty.       | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 14:28:53 |



**US3402139**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:26:34**

[Was this participant screened previously?](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:16 |
| User entered 'No (N)'     | (b) (4)              |                      |
|                           | Tarin Gordon (b) (4) | 01 Aug 2020 14:28:53 |
|                           | (b) (4)              |                      |

**US3402139**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:26:34**

[If Yes, previous participant number](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)                          | 15 Feb 2021 16:53:16 |
| User entered empty.       | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 01 Aug 2020 13:54:07 |

**US3402139**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:26:34**

[Enrollment Trigger](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 09:48:32 |
| User entered 'I'  | System           | 01 Aug 2020 14:28:58 |

**US3402139**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:16 |
| User entered 'Yes (Y)'    | (b) (4)              | 01 Aug 2020 14:28:58 |
|                           | Tarin Gordon (b) (4) |                      |
|                           | (b) (4)              |                      |

**US3402139**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 09 Jun 2021 17:26:34**

[Were any significant conditions reported?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered 'Yes (Y)'    | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:22:23 |

US3402139

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:26:34

[Condition](#)

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)     | 28 Apr 2021 09:48:32 |
| User signature succeeded.  | Frank Eder (b) (4)   | 15 Feb 2021 16:53:16 |
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Hypersensitivity, LLT: Environmental allergy - version MedDRA\\23.0. | Coder Import (b) (4) | 01 Aug 2020 16:26:04 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4) | 01 Aug 2020 16:26:04 |
| Data point term sent to Coder  | System               | 01 Aug 2020 16:24:35 |
| User entered 'ENVIRONMENTAL ALLERGIES'   | Tarin Gordon (b) (4) | 01 Aug 2020 16:24:26 |

**US3402139**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded.  | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered 'UN UNK 2010' | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:24:26 |

**US3402139**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:26:34**

[Start date completely unknown](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered '0'          | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:24:26 |



**US3402139**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:26:34**

[Condition ongoing at study entry](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered 'Yes (Y)'    | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:24:26 |

**US3402139**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered empty.       | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:24:26 |

**US3402139**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:26:34**

[Stop date completely unknown](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered '0'          | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:24:26 |

**US3402139**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 09:48:32 |
| User entered 'Jan 2010' | System           | 01 Aug 2020 16:24:26 |

**US3402139**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 09:48:32 |
| User entered '2010' | System           | 01 Aug 2020 16:24:26 |

**US3402139**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 09:48:32 |
| User entered empty. | System           | 01 Aug 2020 16:24:26 |

**US3402139**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 09:48:32 |
| User entered empty. | System           | 01 Aug 2020 16:24:26 |

US3402139

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:26:34

[Condition](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded.   | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine headache - version MedDRA\\23.0. | (b) (4)<br>Coder Import (b) (4) | 01 Aug 2020 16:32:07 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)            | 01 Aug 2020 16:32:07 |
| Data point term sent to Coder   | System                          | 01 Aug 2020 16:30:37 |
| User entered 'MIGRAINE HEADACHES'   | Tarin Gordon (b) (4)            | 01 Aug 2020 16:29:40 |
|   | (b) (4)                         |                      |



**US3402139**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded.  | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered 'UN UNK 1990' | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:29:40 |

**US3402139**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:26:34**

[Start date completely unknown](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered '0'          | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:29:40 |

**US3402139**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:26:34**

[Condition ongoing at study entry](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered 'Yes (Y)'    | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:29:40 |

**US3402139**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:16 |
| User entered empty.       | (b) (4)              | 01 Aug 2020 16:29:40 |
|                           | Tarin Gordon (b) (4) |                      |
|                           | (b) (4)              |                      |

**US3402139**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:26:34**

[Stop date completely unknown](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered '0'          | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:29:40 |

**US3402139**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 09:48:32 |
| User entered 'Jan 1990' | System           | 01 Aug 2020 16:29:40 |

**US3402139**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 09:48:32 |
| User entered '1990' | System           | 01 Aug 2020 16:29:40 |

**US3402139**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 09:48:32 |
| User entered empty. | System           | 01 Aug 2020 16:29:40 |



**US3402139**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 09:48:32 |
| User entered empty. | System           | 01 Aug 2020 16:29:40 |

US3402139

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:26:34

[Condition](#)

| Audit  | User                         | Time (GMT)           |
|--|------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)             | 28 Apr 2021 09:48:32 |
| User signature succeeded.  | Frank Eder (b) (4)           | 15 Feb 2021 16:53:16 |
| User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0. | (b) (4) (b) (4) (b) (4)      | 01 Aug 2020 16:32:07 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4) (b) (4) | 01 Aug 2020 16:32:07 |
| Data point term sent to Coder  | System                       | 01 Aug 2020 16:30:36 |
| User entered 'POST-MENOPAUSAL'   | Tarin Gordon (b) (4) (b) (4) | 01 Aug 2020 16:30:33 |

**US3402139**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded.  | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered 'UN UNK 2015' | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:30:33 |

**US3402139**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:26:34**

[Start date completely unknown](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered '0'          | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:30:33 |

**US3402139**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:26:34**

[Condition ongoing at study entry](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered 'Yes (Y)'    | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:30:33 |

**US3402139**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered empty.       | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:30:33 |

**US3402139**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:26:34**

[Stop date completely unknown](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered '0'          | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:30:33 |

**US3402139**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 09:48:32 |
| User entered 'Jan 2015' | System           | 01 Aug 2020 16:30:33 |



**US3402139**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 09:48:32 |
| User entered '2015' | System           | 01 Aug 2020 16:30:33 |

**US3402139**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 09:48:32 |
| User entered empty. | System           | 01 Aug 2020 16:30:33 |

**US3402139**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 09:48:32 |
| User entered empty. | System           | 01 Aug 2020 16:30:33 |

US3402139

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:26:34

Condition

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded.  | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User closed query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).   | (b) (4)<br>(b) (4), (b) (6)     | 15 Jan 2021 09:36:22 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knee - version MedDRA\23.0.   | Coder Import (b) (4)<br>(b) (4) | 14 Jan 2021 13:10:50 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.  | Coder Import (b) (4)<br>(b) (4) | 14 Jan 2021 13:10:50 |
| Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'PATIENT HAS OSTEOARTHRITIS OF THE LEFT KNEE' (Site from DM). | Tammy Kohn (b) (4)<br>(b) (4)   | 14 Jan 2021 13:10:32 |
| Data point term sent to Coder  | System                          | 14 Jan 2021 13:10:25 |
| Coding entries removed.  | Tammy Kohn (b) (4)<br>(b) (4)   | 14 Jan 2021 13:09:30 |
| User entered 'OSTEOARTHRITIS LEFT KNEE ARTHRITIS' reason for change: Data Entry Error  | Tammy Kohn (b) (4)<br>(b) (4)   | 14 Jan 2021 13:09:30 |
| User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).   | (b) (4), (b) (6)                | 13 Jan 2021 09:32:18 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Knee arthritis - version MedDRA\23.0.  | Coder Import (b) (4)<br>(b) (4) | 07 Nov 2020 13:22:30 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.  | Coder Import (b) (4)<br>(b) (4) | 07 Nov 2020 13:22:30 |
| Data point term sent to Coder  | System                          | 07 Nov 2020 13:21:33 |

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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**US3402139**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:26:34**

[Condition](#)

| Audit                              | User                      | Time (GMT)           |
|------------------------------------|---------------------------|----------------------|
| User entered 'Left knee arthritis' | Jennifer Molstead (b) (4) | 07 Nov 2020 13:20:55 |
|                                    | (b) (4)                   |                      |

**US3402139**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 28 Apr 2021 09:48:32 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Feb 2021 16:53:16 |
| User entered 'un UNK 2002' | (b) (4)<br>Jennifer Molstead (b) (4) | 07 Nov 2020 13:20:55 |

**US3402139**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:26:34**

[Start date completely unknown](#)

| Audit                     | User                      | Time (GMT)           |
|---------------------------|---------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)          | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)        | 15 Feb 2021 16:53:16 |
| User entered '0'          | Jennifer Molstead (b) (4) | 07 Nov 2020 13:20:55 |

**US3402139**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:26:34**

[Condition ongoing at study entry](#)

| Audit                     | User                      | Time (GMT)           |
|---------------------------|---------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)          | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)        | 15 Feb 2021 16:53:16 |
| User entered 'Yes (Y)'    | (b) (4)                   | 07 Nov 2020 13:20:55 |
|                           | Jennifer Molstead (b) (4) |                      |
|                           | (b) (4)                   |                      |



**US3402139**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit                     | User               | Time (GMT)                                     |
|---------------------------|--------------------|--|
| Data hard locked.         | (b) (4), (b) (6)   | 28 Apr 2021 09:48:32                           |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 16:53:16                           |
| User entered empty.       | (b) (4)            | Jennifer Molstead (b) (4) 07 Nov 2020 13:20:55 |
|                           | (b) (4)            |  |

**US3402139**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:26:34**

[Stop date completely unknown](#)

| Audit                     | User                      | Time (GMT)           |
|---------------------------|---------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)          | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)        | 15 Feb 2021 16:53:16 |
| User entered '0'          | (b) (4)                   |                      |
|                           | Jennifer Molstead (b) (4) | 07 Nov 2020 13:20:55 |
|                           | (b) (4)                   |                      |

**US3402139**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 09:48:32 |
| User entered 'Jan 2002' | System           | 07 Nov 2020 13:20:55 |

**US3402139**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 09:48:32 |
| User entered '2002' | System           | 07 Nov 2020 13:20:55 |

**US3402139**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 09:48:32 |
| User entered empty. | System           | 07 Nov 2020 13:20:55 |

**US3402139**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 09:48:32 |
| User entered empty. | System           | 07 Nov 2020 13:20:55 |

**US3402139**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:26:34**

[Were vital signs assessed?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered 'Yes (Y)'    | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:23:24 |

US3402139

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:34

Date of assessment (*dd MMM yyyy*)

| Audit   | User               | Time (GMT)           |
|---|--------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)   | 28 Apr 2021 09:48:32 |
| User signature succeeded.                                     | Frank Eder (b) (4) | 15 Feb 2021 16:53:16 |
| User entered '01 Aug 2020' reason for change: New Information | (b) (4)            | 11 Nov 2020 12:18:12 |
| User entered '1 Aug 2020'                                     | Traci Hull (b) (4) | 01 Aug 2020 16:23:24 |
|   | (b) (4)            |                      |



**US3402139**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:16 |
| User entered '09:45'      | (b) (4)              | 01 Aug 2020 16:23:24 |
|                           | Tarin Gordon (b) (4) |                      |
|                           | (b) (4)              |                      |

**US3402139**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 09:48:32 |
| User entered '01 Aug 2020 09:45' | System           | 11 Nov 2020 12:18:12 |
| User entered '1 Aug 2020 09:45'  | System           | 01 Aug 2020 16:23:24 |

US3402139

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:34

Height (xxx.x)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:16 |
| User entered '169.5' cm   | (b) (4)              |                      |
|                           | Tarin Gordon (b) (4) | 01 Aug 2020 16:23:24 |
| DataPoint set to visible. | (b) (4)              |                      |
|                           | System               | 01 Aug 2020 14:28:58 |

US3402139

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:34

Weight (xxx.x)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:16 |
| User entered '71.2' kg    | (b) (4)              |                      |
|                           | Tarin Gordon (b) (4) | 01 Aug 2020 16:23:24 |
| DataPoint set to visible. | (b) (4)              |                      |
|                           | System               | 01 Aug 2020 14:28:58 |

US3402139

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:34

BMI (xxx.x)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6) | 28 Apr 2021 09:48:32 |
| Amendment Manager: User entered '24.78224' | System           | 16 Sep 2020 23:40:18 |
| User entered '24.8'                        | System           | 01 Aug 2020 16:23:24 |
| DataPoint set to visible.                  | System           | 01 Aug 2020 14:28:58 |

**US3402139**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:26:34**

[BMI units](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 28 Apr 2021 09:48:32 |
| User entered 'kg/m2'      | System           | 01 Aug 2020 16:23:24 |
| DataPoint set to visible. | System           | 01 Aug 2020 14:28:58 |

US3402139

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:34

Temperature (xxx.x)

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)     | 28 Apr 2021 09:48:32 |
| User signature succeeded.   | Frank Eder (b) (4)   | 15 Feb 2021 16:53:16 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4)              | 20 Dec 2020 15:19:29 |
| User entered '36.8' C   | Tarin Gordon (b) (4) | 01 Aug 2020 16:23:24 |
|   | (b) (4)              |                      |

**US3402139**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:26:34**

[Route of measurement](#)

| Audit  | User               | Time (GMT)           |
|--|--------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)   | 28 Apr 2021 09:48:32 |
| User signature succeeded.                              | Frank Eder (b) (4) | 15 Feb 2021 16:53:16 |
| User entered empty; reason for change Data Entry Error | (b) (4)            | 20 Dec 2020 15:19:29 |
| User entered 'Oral (Oral)'                             | Tammy Kohn (b) (4) | 01 Aug 2020 16:23:24 |
|  | (b) (4)            |                      |



**US3402139**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:26:34**

[If Other, specify](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered empty.       | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:23:24 |

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:34

[Pulse \(xxx\)](#)

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)     | 28 Apr 2021 09:48:32 |
| User signature succeeded.   | Frank Eder (b) (4)   | 15 Feb 2021 16:53:16 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4)              | 20 Dec 2020 15:19:29 |
| User entered '66'   | Tarin Gordon (b) (4) | 01 Aug 2020 16:23:24 |
|   | (b) (4)              |                      |

**US3402139**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:26:34**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 28 Apr 2021 09:48:32 |
| User entered 'bpm' | System           | 01 Aug 2020 16:23:24 |

US3402139

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:34

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

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)     | 28 Apr 2021 09:48:32 |
| User signature succeeded.   | Frank Eder (b) (4)   | 15 Feb 2021 16:53:16 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4)              | 20 Dec 2020 15:19:29 |
| User entered '14'   | Tarin Gordon (b) (4) | 01 Aug 2020 16:23:24 |
|   | (b) (4)              |                      |

**US3402139**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:26:34**

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 28 Apr 2021 09:48:32 |
| User entered 'breaths/min' | System           | 01 Aug 2020 16:23:24 |

US3402139

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:34

[Systolic Blood Pressure \(xxx\)](#)

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)     | 28 Apr 2021 09:48:32 |
| User signature succeeded.   | Frank Eder (b) (4)   | 15 Feb 2021 16:53:16 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4)              | 20 Dec 2020 15:19:29 |
| User entered '127'  | Tarin Gordon (b) (4) | 01 Aug 2020 16:23:24 |
|   | (b) (4)              |                      |

**US3402139**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:26:34**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 09:48:32 |
| User entered 'mmHg' | System           | 01 Aug 2020 16:23:24 |

**US3402139**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:26:34**

[Diastolic Blood Pressure \(xxx\)](#)

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)     | 28 Apr 2021 09:48:32 |
| User signature succeeded.   | Frank Eder (b) (4)   | 15 Feb 2021 16:53:16 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4)              | 20 Dec 2020 15:19:29 |
| User entered '79'   | Tarin Gordon (b) (4) | 01 Aug 2020 16:23:24 |
|   | (b) (4)              |                      |



**US3402139**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:26:34**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 09:48:32 |
| User entered 'mmHg' | System           | 01 Aug 2020 16:23:24 |

**US3402139**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:26:34**

[Height \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 09:48:32 |

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:34

Weight (derived)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 09:48:32 |

**US3402139**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:26:34**

[Was the physical examination performed?](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:16 |
| User entered 'Yes (Y)'    | (b) (4)              | 01 Aug 2020 16:30:54 |
|                           | Tarin Gordon (b) (4) |                      |
|                           | (b) (4)              |                      |

US3402139

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:26:34

Date of examination (dd MMM yyyy)

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)     | 28 Apr 2021 09:48:32 |
| User signature succeeded.  | Frank Eder (b) (4)   | 15 Feb 2021 16:53:16 |
| User entered '01 Aug 2020' reason for change: New Information  | Traci Hull (b) (4)   | 11 Nov 2020 12:18:23 |
| Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).    | (b) (4), (b) (6)     | 06 Sep 2020 12:18:04 |
| User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System). |                      | 31 Aug 2020 13:34:26 |
| User entered '1 Aug 2020'  | Tarin Gordon (b) (4) | 01 Aug 2020 16:30:54 |

US3402139

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:26:34

Date of assessment (*dd MMM yyyy*)

| Audit   | User               | Time (GMT)           |
|---|--------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)   | 28 Apr 2021 09:48:32 |
| User signature succeeded.                                     | Frank Eder (b) (4) | 15 Feb 2021 16:53:16 |
| User entered '01 Aug 2020' reason for change: New Information | (b) (4)            | 11 Nov 2020 12:18:39 |
| User entered '1 Aug 2020'                                     | Traci Hull (b) (4) | 01 Aug 2020 16:31:12 |
|   | (b) (4)            |                      |

**US3402139**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 17:26:34**

[Is the participant of childbearing potential?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered 'No (N)'     | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:31:12 |

**US3402139**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 17:26:34**

[If No, what is the reason?](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.                                | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded.                        | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered 'Post-menopausal (POST-MENOPAUSAL)' | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:31:12 |



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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:26:34

If Partner medically sterile or Other, specify

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered empty.       | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:31:12 |

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:26:34

If Surgically sterile, date of surgery (*dd MMM yyyy*)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered empty.       | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:31:12 |

**US3402139**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 17:26:34**

[Date of surgery unknown](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered '0'          | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:31:12 |

US3402139

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:26:34

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

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded.  | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered 'UN UNK 2015' | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:31:12 |

**US3402139**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 17:26:34**

[Date of last menstruation unknown](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered '0'          | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:31:12 |

US3402139

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:34

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

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered 'No (N)'     | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:33:25 |

US3402139

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:34

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

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered 'No (N)'     | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:33:25 |

US3402139

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:34

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered 'No (N)'     | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:33:25 |



US3402139

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:34

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

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:16 |
| User entered 'No (N)'     | Tarin Gordon (b) (4) | 01 Aug 2020 16:33:25 |

US3402139

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:34

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

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:16 |
| User entered 'No (N)'     | (b) (4)              | 01 Aug 2020 16:33:25 |
|                           | Tarin Gordon (b) (4) |                      |
|                           | (b) (4)              |                      |

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Folder: Screening

Form: Risk of Exposure

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

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:16 |
| User entered 'Yes (Y)'    | Tarin Gordon (b) (4) | 01 Aug 2020 16:33:25 |

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Folder: Screening

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**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:16 |
| User entered 'No (N)'     | Tarin Gordon (b) (4) | 01 Aug 2020 16:33:25 |

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**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:16 |
| User entered 'No (N)'     | Tarin Gordon (b) (4) | 01 Aug 2020 16:33:25 |

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Folder: Screening

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

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered 'No (N)'     | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:33:25 |

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Folder: Screening

Form: Risk of Exposure

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**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:16 |
| User entered 'No (N)'     | Tarin Gordon (b) (4) | 01 Aug 2020 16:33:25 |

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Folder: Screening

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**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:16 |
| User entered 'No (N)'     | Tarin Gordon (b) (4) | 01 Aug 2020 16:33:25 |



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**Folder: Screening**

**Form: Risk of Exposure**

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**Other**

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered 'No (N)'     | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:33:25 |

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[Specify](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:16 |
| User entered empty.       | (b) (4)              | 01 Aug 2020 16:33:25 |
|                           | Tarin Gordon (b) (4) |                      |
|                           | (b) (4)              |                      |

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No Risk Identified

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered 'I'          | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:33:25 |

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Folder: Screening

Form: Risk of Exposure

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

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered '0'          | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:33:25 |

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Folder: Screening

Form: Risk of Exposure

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**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:16 |
| User entered '0'          | Tarin Gordon (b) (4) | 01 Aug 2020 16:33:25 |

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:34

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

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered '0'          | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:33:25 |

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:34

**Resides in low density, multi-family setting without** (e.g., apartments complex without shared entrances or elevators, duplexes)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:16 |
| User entered '0'          | Tarin Gordon (b) (4) | 01 Aug 2020 16:33:25 |

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:34

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

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered '0'          | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:33:25 |



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Folder: Screening

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[Other](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered '0'          | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:33:25 |

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:16 |
| User entered empty.       | (b) (4)              |                      |
|                           | Tarin Gordon (b) (4) | 01 Aug 2020 16:33:25 |
|                           | (b) (4)              |                      |

**US3402139**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:26:34**

[Was this visit performed?](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:21 |
| User entered 'Yes (Y)'    | (b) (4)              |                      |
|                           | Tarin Gordon (b) (4) | 01 Aug 2020 16:33:56 |
|                           | (b) (4)              |                      |

**US3402139**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit   | User               | Time (GMT)           |
|---|--------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded.                                     | Frank Eder (b) (4) | 15 Feb 2021 16:53:21 |
| User entered '01 Aug 2020' reason for change: New Information | (b) (4)            | 11 Nov 2020 12:18:59 |
| User entered '1 Aug 2020'                                     | Traci Hull (b) (4) | 01 Aug 2020 16:33:56 |
|   | (b) (4)            |                      |

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:26:34

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

| Audit                          | User                            | Time (GMT)           |
|--------------------------------|---------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                | 27 Mar 2021 18:38:17 |
| User signature succeeded.      | Frank Eder (b) (4)              | 15 Feb 2021 16:53:21 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:33:56 |

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**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:26:34**

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered 'VISIT1' | System           | 01 Aug 2020 16:33:56 |

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:26:34

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

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 27 Mar 2021 18:38:17 |
| User signature succeeded.  | Frank Eder (b) (4)                          | 15 Feb 2021 16:53:21 |
| User entered '01 AUG 2020' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 01 Aug 2020 13:59:06 |

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:26:34

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

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                 | 27 Mar 2021 18:38:17 |
| User signature succeeded.  | Frank Eder (b) (4)               | 15 Feb 2021 16:53:21 |
| Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | (b) (4)<br>System                | 21 Aug 2020 01:36:09 |
| Amendment Manager: Data point set to conformant.   | System                           | 21 Aug 2020 01:36:08 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System).                    | System                           | 01 Aug 2020 13:59:06 |
| User entered '100518' (non-conformant).  | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 01 Aug 2020 13:59:06 |



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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:26:34

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

| Audit   | User               | Time (GMT)           |
|---|--------------------|----------------------|
| Data hard locked.                                     | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded.                             | Frank Eder (b) (4) | 15 Feb 2021 16:53:21 |
| User entered '>=18 and <65 years and not at risk (1)' | (b) (4)            |                      |
|   | RWS_ENDPOINT       | 01 Aug 2020 13:59:06 |
|   | ENDPOINT (b) (4)   |                      |
|   |                    |                      |

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**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:21 |
| User entered 'No (N)'     | Tarin Gordon (b) (4) | 01 Aug 2020 16:34:51 |

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Folder: Visit 1 Day 1

Form: Randomization

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

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:21 |
| User entered 'No (N)'     | Tarin Gordon (b) (4) | 01 Aug 2020 16:34:51 |

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**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:21 |
| User entered 'No (N)'     | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:34:51 |

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**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:26:34**

[Diabetes \(Type I, Type 2, or gestational\)](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:21 |
| User entered 'No (N)'     | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:34:51 |

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:26:34

[Liver Disease](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:21 |
| User entered 'No (N)'     | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:34:51 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:26:34

[Height](#)

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)     | 27 Mar 2021 18:38:17 |
| User signature succeeded.   | Frank Eder (b) (4)   | 15 Feb 2021 16:53:21 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4)              | 20 Dec 2020 15:19:49 |
| User entered '169.5' cm   | Tarin Gordon (b) (4) | 01 Aug 2020 16:37:46 |
|   | (b) (4)              |                      |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:26:34

[Weight](#)

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)     | 27 Mar 2021 18:38:17 |
| User signature succeeded.   | Frank Eder (b) (4)   | 15 Feb 2021 16:53:21 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4)              | 20 Dec 2020 15:19:49 |
| User entered '71.2' kg  | Tarin Gordon (b) (4) | 01 Aug 2020 16:37:46 |
|   | (b) (4)              |                      |



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:26:34

[Height](#)

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)     | 27 Mar 2021 18:38:17 |
| User signature succeeded.   | Frank Eder (b) (4)   | 15 Feb 2021 16:53:21 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4)              | 20 Dec 2020 15:19:49 |
| User entered '169.5' cm   | Tarin Gordon (b) (4) | 01 Aug 2020 16:37:46 |
|   | (b) (4)              |                      |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:26:34

[Weight](#)

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)     | 27 Mar 2021 18:38:17 |
| User signature succeeded.   | Frank Eder (b) (4)   | 15 Feb 2021 16:53:21 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4)              | 20 Dec 2020 15:19:49 |
| User entered '71.2' kg  | Tarin Gordon (b) (4) | 01 Aug 2020 16:37:46 |
|   | (b) (4)              |                      |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:34

[Timepoint](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.                                | (b) (4), (b) (6)                | 27 Mar 2021 18:38:17 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:37:46 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:34

[Were vital signs assessed?](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:21 |
| User entered 'Yes (Y)'    | (b) (4)              |                      |
|                           | Tarin Gordon (b) (4) | 01 Aug 2020 16:37:46 |
|                           | (b) (4)              |                      |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:34

Date of assessment (*dd MMM yyyy*)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                | 27 Mar 2021 18:38:17 |
| User signature succeeded.                                     | Frank Eder (b) (4)              | 15 Feb 2021 16:53:21 |
| User entered '01 Aug 2020' reason for change: New Information | (b) (4)<br>Traci Hull (b) (4)   | 11 Nov 2020 12:19:24 |
| User entered '1 Aug 2020'                                     | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:37:46 |
|   | (b) (4)                         |                      |

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:21 |
| User entered '09:45'      | (b) (4)              |                      |
|                           | Tarin Gordon (b) (4) | 01 Aug 2020 16:37:46 |
|                           | (b) (4)              |                      |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:34

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered '01 Aug 2020 09:45' | System           | 11 Nov 2020 12:19:24 |
| User entered '1 Aug 2020 09:45'  | System           | 01 Aug 2020 16:37:46 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:34

Temperature (xxx.x)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:21 |
| User entered '36.8' C     | (b) (4)              |                      |
|                           | Tarin Gordon (b) (4) | 01 Aug 2020 16:37:46 |
|                           | (b) (4)              |                      |



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:34

[Route of measurement](#)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                | 27 Mar 2021 18:38:17 |
| User signature succeeded.  | Frank Eder (b) (4)              | 15 Feb 2021 16:53:21 |
| User entered 'Oral (Oral)' | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:37:46 |

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:26:34**

[If Other, specify](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:21 |
| User entered empty.       | (b) (4)              |                      |
|                           | Tarin Gordon (b) (4) | 01 Aug 2020 16:37:46 |
|                           | (b) (4)              |                      |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:34

[Pulse \(xxx\)](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:21 |
| User entered '66'         | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:37:46 |

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:26:34**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered 'bpm' | System           | 01 Aug 2020 16:37:46 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:34

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

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:21 |
| User entered '14'         | (b) (4)              |                      |
|                           | Tarin Gordon (b) (4) | 01 Aug 2020 16:37:46 |
|                           | (b) (4)              |                      |

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:34

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered 'breaths/min' | System           | 01 Aug 2020 16:37:46 |

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:34

Systolic Blood Pressure (xxx)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:21 |
| User entered '127'        | (b) (4)              |                      |
|                           | Tarin Gordon (b) (4) | 01 Aug 2020 16:37:46 |
|                           | (b) (4)              |                      |

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:34

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered 'mmHg' | System           | 01 Aug 2020 16:37:46 |



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:34

Diastolic Blood Pressure (xxx)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:21 |
| User entered '79'         | Tarin Gordon (b) (4) | 01 Aug 2020 16:37:46 |

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:34

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered 'mmHg' | System           | 01 Aug 2020 16:37:46 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:26:34

[Height](#)

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)     | 27 Mar 2021 18:38:17 |
| User signature succeeded.   | Frank Eder (b) (4)   | 15 Feb 2021 16:53:21 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4)              | 20 Dec 2020 15:19:49 |
| User entered '169.5' cm   | Tarin Gordon (b) (4) | 01 Aug 2020 16:37:46 |
|   | (b) (4)              |                      |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:26:34

[Weight](#)

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)     | 27 Mar 2021 18:38:17 |
| User signature succeeded.   | Frank Eder (b) (4)   | 15 Feb 2021 16:53:21 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4)              | 20 Dec 2020 15:19:49 |
| User entered '71.2' kg  | Tarin Gordon (b) (4) | 01 Aug 2020 16:37:46 |
|   | (b) (4)              |                      |

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:34

[Timepoint](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6)                | 27 Mar 2021 18:38:17 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:37:46 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:34

[Were vital signs assessed?](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:21 |
| User entered 'Yes (Y)'    | (b) (4)              |                      |
|                           | Tarin Gordon (b) (4) | 01 Aug 2020 16:37:46 |
|                           | (b) (4)              |                      |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:34

Date of assessment (*dd MMM yyyy*)

| Audit   | User               | Time (GMT)           |
|---|--------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded.                                     | Frank Eder (b) (4) | 15 Feb 2021 16:53:21 |
| User entered '01 Aug 2020' reason for change: New Information | (b) (4)            | 11 Nov 2020 12:19:24 |
| User entered '1 Aug 2020'                                     | Traci Hull (b) (4) | 01 Aug 2020 16:37:46 |
|   | (b) (4)            |                      |

US3402139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:34

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

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                | 27 Mar 2021 18:38:17 |
| User signature succeeded.   | Frank Eder (b) (4)              | 15 Feb 2021 16:53:21 |
| User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).            | (b) (4)<br>(b) (4), (b) (6)     | 17 Aug 2020 19:36:25 |
| Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30 MIN' (Site from System). | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:38:27 |
| User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).     |                                 | 01 Aug 2020 16:37:46 |
| User entered '10:57'  | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:37:46 |



**US3402139**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered '01 Aug 2020 10:57' | System           | 11 Nov 2020 12:19:24 |
| User entered '1 Aug 2020 10:57'  | System           | 01 Aug 2020 16:37:46 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:34

Temperature (xxx.x)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:21 |
| User entered '36.8' C     | (b) (4)              |                      |
|                           | Tarin Gordon (b) (4) | 01 Aug 2020 16:37:46 |
|                           | (b) (4)              |                      |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:34

[Route of measurement](#)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                | 27 Mar 2021 18:38:17 |
| User signature succeeded.  | Frank Eder (b) (4)              | 15 Feb 2021 16:53:21 |
| User entered 'Oral (Oral)' | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:37:46 |

**US3402139**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:26:34**

[If Other, specify](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:21 |
| User entered empty.       | (b) (4)              |                      |
|                           | Tarin Gordon (b) (4) | 01 Aug 2020 16:37:46 |
|                           | (b) (4)              |                      |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:34

[Pulse \(xxx\)](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:21 |
| User entered '87'         | (b) (4)              |                      |
|                           | Tarin Gordon (b) (4) | 01 Aug 2020 16:37:46 |
|                           | (b) (4)              |                      |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:34

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered 'bpm' | System           | 01 Aug 2020 16:37:46 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:34

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

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:21 |
| User entered '14'         | (b) (4)              |                      |
|                           | Tarin Gordon (b) (4) | 01 Aug 2020 16:37:46 |
|                           | (b) (4)              |                      |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:34

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered 'breaths/min' | System           | 01 Aug 2020 16:37:46 |



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:34

Systolic Blood Pressure (xxx)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:21 |
| User entered '130'        | Tarin Gordon (b) (4) | 01 Aug 2020 16:37:46 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:34

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered 'mmHg' | System           | 01 Aug 2020 16:37:46 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:34

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:21 |
| User entered '87'         | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:37:46 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:34

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered 'mmHg' | System           | 01 Aug 2020 16:37:46 |

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:26:34

[Was the physical examination performed?](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:16 |
| User entered 'Yes (Y)'    | (b) (4)              |                      |
|                           | Tarin Gordon (b) (4) | 01 Aug 2020 16:38:37 |
|                           | (b) (4)              |                      |

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:26:34

Date of examination (dd MMM yyyy)

| Audit   | User               | Time (GMT)           |
|---|--------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded.                                     | Frank Eder (b) (4) | 15 Feb 2021 16:53:16 |
| User entered '01 Aug 2020' reason for change: New Information | (b) (4)            | 11 Nov 2020 12:19:36 |
| User entered '1 Aug 2020'                                     | Traci Hull (b) (4) | 01 Aug 2020 16:38:37 |
|   | (b) (4)            |                      |

US3402139

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:26:34

[Was study treatment given?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered 'Yes (Y)'    | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 14:29:27 |

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:26:34

[If No, reason not given](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:16 |
| User entered empty.       | (b) (4)              |                      |
|                           | Tarin Gordon (b) (4) | 01 Aug 2020 14:29:27 |
|                           | (b) (4)              |                      |



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Folder: Visit 1 Day 1

Form: Exposure

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

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:16 |
| User entered empty.       | Tarin Gordon (b) (4) | 01 Aug 2020 14:29:27 |

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:26:34

[What was the study treatment?](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| Data hard locked.                   | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered 'MRNA-1273 OR PLACEBO' | System           | 01 Aug 2020 14:29:27 |

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:26:34

What was the treatment date? (dd MMM yyyy)

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)     | 27 Mar 2021 18:38:17 |
| User signature succeeded.                                     | Frank Eder (b) (4)   | 15 Feb 2021 16:53:16 |
| User entered '01 Aug 2020' reason for change: New Information | Traci Hull (b) (4)   | 11 Nov 2020 12:19:52 |
| User entered '1 Aug 2020'                                     | Tarin Gordon (b) (4) | 01 Aug 2020 14:29:27 |

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:26:34

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

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered '10:25'      | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 14:29:27 |

**US3402139**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered '01 Aug 2020 10:25' | System           | 11 Nov 2020 12:19:52 |
| User entered '1 Aug 2020 10:25'  | System           | 01 Aug 2020 14:29:27 |

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:26:34

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

| Audit                              | User                 | Time (GMT)           |
|------------------------------------|----------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)     | 27 Mar 2021 18:38:17 |
| User signature succeeded.          | Frank Eder (b) (4)   | 15 Feb 2021 16:53:16 |
| User entered 'Left Arm (LEFT ARM)' | Tarin Gordon (b) (4) | 01 Aug 2020 14:29:27 |

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:26:34

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered 'ONCE' | System           | 01 Aug 2020 14:29:27 |

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:26:34

What was the route of administration for the study treatment?

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered 'INTRAMUSCULAR' | System           | 01 Aug 2020 14:29:27 |



**US3402139**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:26:34**

[Was the sample collected?](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:16 |
| User entered 'Yes (Y)'    | (b) (4)              |                      |
|                           | Tarin Gordon (b) (4) | 01 Aug 2020 16:39:50 |
|                           | (b) (4)              |                      |

US3402139

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:34

Collection date (*dd MMM yyyy*)

| Audit   | User               | Time (GMT)           |
|---|--------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded.                                     | Frank Eder (b) (4) | 15 Feb 2021 16:53:16 |
| User entered '01 Aug 2020' reason for change: New Information | (b) (4)            | 11 Nov 2020 12:20:04 |
| User entered '1 Aug 2020'                                     | Traci Hull (b) (4) | 01 Aug 2020 16:39:50 |
|   | (b) (4)            |                      |

**US3402139**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:26:34**

[Collection time \(00:00-23:59\)](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:16 |
| User entered '10:10'      | (b) (4)              |                      |
|                           | Tarin Gordon (b) (4) | 01 Aug 2020 16:39:50 |
|                           | (b) (4)              |                      |

**US3402139**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered '01 Aug 2020 10:10' | System           | 11 Nov 2020 12:20:04 |
| User entered '1 Aug 2020 10:10'  | System           | 01 Aug 2020 16:39:50 |

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:26:34

Collection date (*dd MMM yyyy*)

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)     | 27 Mar 2021 18:38:17 |
| User signature succeeded.                                     | Frank Eder (b) (4)   | 15 Feb 2021 16:53:16 |
| User entered '01 Aug 2020' reason for change: New Information | Traci Hull (b) (4)   | 11 Nov 2020 12:20:19 |
| User entered '1 Aug 2020'                                     | Tarin Gordon (b) (4) | 01 Aug 2020 16:39:18 |

**US3402139**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:26:34**

[Lab Test](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                | 27 Mar 2021 18:38:17 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:39:18 |

**US3402139**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:26:34**

[Was the sample collected?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered 'Yes (Y)'    | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:39:18 |

**US3402139**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:16 |
| User entered '09:55'      | Tarin Gordon (b) (4) | 01 Aug 2020 16:39:18 |



**US3402139**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered '01 Aug 2020 09:55' | System           | 11 Nov 2020 12:20:19 |
| User entered '1 Aug 2020 09:55'  | System           | 01 Aug 2020 16:39:18 |

**US3402139**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:26:34**

[Lab Test](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                | 27 Mar 2021 18:38:17 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:39:18 |

**US3402139**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:26:34**

[Was the sample collected?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered 'No (N)'     | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:39:18 |

**US3402139**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:16 |
| User entered empty.       | (b) (4)<br>Tarin Gordon (b) (4) | 01 Aug 2020 16:39:18 |

**US3402139**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:26:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered empty. | System           | 01 Aug 2020 16:39:18 |

US3402139

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:26:34

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

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:16 |
| User entered 'Yes (Y)'    | (b) (4)              |                      |
|                           | Tarin Gordon (b) (4) | 01 Aug 2020 16:39:36 |
|                           | (b) (4)              |                      |

US3402139

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:26:34

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered 'I'  | System           | 01 Aug 2020 16:39:36 |

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.   | System           | 01 Aug 2020 14:29:27 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 01 Aug 2020 14:29:27 |



US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T10:58:49', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '1849e445-003f-4146-8008-a666886025da' | System           | 01 Aug 2020 14:59:07 |
| User entered 'Yes (Y)'  | System           | 01 Aug 2020 14:59:07 |

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

Please record your **TEMPERATURE** in °F

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T10:58:54', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '1849e445-003f-4146-8008-a666886025da' User entered '98.3' | System           | 01 Aug 2020 14:59:07 |
|   | System           | 01 Aug 2020 14:59:07 |

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

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

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T10:59:00', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '1849e445-003f-4146-8008-a666886025da' | System           | 01 Aug 2020 14:59:07 |
| User entered 'No (N)'   | System           | 01 Aug 2020 14:59:07 |

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T10:59:04', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '1849e445-003f-4146-8008-a666886025da' | System           | 01 Aug 2020 14:59:07 |
| User entered '01 Aug 2020 10:59'  | System           | 01 Aug 2020 14:59:07 |

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '01 Aug 2020 10:45' | System           | 01 Aug 2020 14:29:27 |

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '01 Aug 2020 13:15' | System           | 01 Aug 2020 14:29:27 |

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.                                | System           | 01 Aug 2020 14:29:27 |
| User entered 'Day 1, after vaccination (at home)' | System           | 01 Aug 2020 14:29:27 |

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T20:37:31', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '17ff2a52-becc-4cbc-8263-b7b48912971d' | System           | 02 Aug 2020 00:37:51 |
| User entered 'Yes (Y)'  | System           | 02 Aug 2020 00:37:51 |



US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

Please record your **TEMPERATURE** in °F

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T20:37:39', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '17ff2a52-becc-4cbc-8263-b7b48912971d' | System           | 02 Aug 2020 00:37:51 |
| User entered '98.7'   | System           | 02 Aug 2020 00:37:51 |

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

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

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T20:37:43', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '17ff2a52-becc-4cbc-8263-b7b48912971d' | System           | 02 Aug 2020 00:37:51 |
| User entered 'No (N)'   | System           | 02 Aug 2020 00:37:51 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T20:37:46', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '17ff2a52-becc-4cbc-8263-b7b48912971d' | System           | 02 Aug 2020 00:37:51 |
| User entered '01 Aug 2020 20:37'  | System           | 02 Aug 2020 00:37:51 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '01 Aug 2020 14:10' | System           | 01 Aug 2020 14:29:27 |

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '02 Aug 2020 11:59' | System           | 01 Aug 2020 14:29:27 |

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.   | System           | 01 Aug 2020 14:29:27 |
| User entered 'Day 2' | System           | 01 Aug 2020 14:29:27 |

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:26:34

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-02T12:00:44', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '287c9444-2e1b-4414-98cc-abb8ef397d1b' | System           | 02 Aug 2020 16:00:56 |
| User entered 'Yes (Y)'  | System           | 02 Aug 2020 16:00:56 |

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:26:34

Please record your **TEMPERATURE** in °F

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-02T12:00:48', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '287c9444-2e1b-4414-98cc-abb8ef397d1b' User entered '98.3' | System           | 02 Aug 2020 16:00:56 |
|   | System           | 02 Aug 2020 16:00:56 |



US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:26:34

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

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-02T12:00:51', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '287c9444-2e1b-4414-98cc-abb8ef397d1b' | System           | 02 Aug 2020 16:00:56 |
| User entered 'No (N)'   | System           | 02 Aug 2020 16:00:56 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-02T12:00:54', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '287c9444-2e1b-4414-98cc-abb8ef397d1b' | System           | 02 Aug 2020 16:00:56 |
| User entered '02 Aug 2020 12:00'  | System           | 02 Aug 2020 16:00:56 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '02 Aug 2020 12:00' | System           | 01 Aug 2020 14:29:27 |

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:26:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '03 Aug 2020 11:59' | System           | 01 Aug 2020 14:29:27 |

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.   | System           | 01 Aug 2020 14:29:27 |
| User entered 'Day 3' | System           | 01 Aug 2020 14:29:27 |

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:26:34

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-03T12:35:16', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '8b372f31-68f5-4782-9daf-3c95ed19b0a2' | System           | 03 Aug 2020 16:35:52 |
| User entered 'Yes (Y)'  | System           | 03 Aug 2020 16:35:52 |

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:26:34

Please record your **TEMPERATURE** in °F

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-03T12:35:42', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '8b372f31-68f5-4782-9daf-3c95ed19b0a2' | System           | 03 Aug 2020 16:35:52 |
| User entered '97.5'   | System           | 03 Aug 2020 16:35:52 |

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:26:34

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

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-03T12:35:45', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '8b372f31-68f5-4782-9daf-3c95ed19b0a2' | System           | 03 Aug 2020 16:35:52 |
| User entered 'No (N)'   | System           | 03 Aug 2020 16:35:52 |



**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-03T12:35:50', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '8b372f31-68f5-4782-9daf-3c95ed19b0a2' | System           | 03 Aug 2020 16:35:52 |
| User entered '03 Aug 2020 12:35'  | System           | 03 Aug 2020 16:35:52 |

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:26:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '03 Aug 2020 12:00' | System           | 01 Aug 2020 14:29:27 |

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:26:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '04 Aug 2020 11:59' | System           | 01 Aug 2020 14:29:27 |

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.   | System           | 01 Aug 2020 14:29:27 |
| User entered 'Day 4' | System           | 01 Aug 2020 14:29:27 |

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:26:34

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-04T12:01:59', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '13d7c822-a783-4be1-894f-56c472058035' | System           | 04 Aug 2020 16:02:14 |
| User entered 'Yes (Y)'  | System           | 04 Aug 2020 16:02:14 |

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:26:34

Please record your **TEMPERATURE** in °F

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-04T12:02:03', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '13d7c822-a783-4be1-894f-56c472058035' | System           | 04 Aug 2020 16:02:14 |
| User entered '98.0'   | System           | 04 Aug 2020 16:02:14 |

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:26:34

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

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-04T12:02:08', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '13d7c822-a783-4be1-894f-56c472058035' | System           | 04 Aug 2020 16:02:14 |
| User entered 'No (N)'   | System           | 04 Aug 2020 16:02:14 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-04T12:02:11', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '13d7c822-a783-4be1-894f-56c472058035' | System           | 04 Aug 2020 16:02:14 |
| User entered '04 Aug 2020 12:02'  | System           | 04 Aug 2020 16:02:14 |



US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:26:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '04 Aug 2020 12:00' | System           | 01 Aug 2020 14:29:27 |

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:26:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '05 Aug 2020 11:59' | System           | 01 Aug 2020 14:29:27 |

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.   | System           | 01 Aug 2020 14:29:27 |
| User entered 'Day 5' | System           | 01 Aug 2020 14:29:27 |

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:26:34

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-05T12:04:53', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '37150400-9214-4d40-bd51-da645ea1e972' | System           | 05 Aug 2020 16:05:06 |
| User entered 'Yes (Y)'  | System           | 05 Aug 2020 16:05:06 |

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:26:34

Please record your **TEMPERATURE** in °F

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-05T12:04:57', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '37150400-9214-4d40-bd51-da645ea1e972' | System           | 05 Aug 2020 16:05:06 |
| User entered '98.3'   | System           | 05 Aug 2020 16:05:06 |

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:26:34

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

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-05T12:04:59', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '37150400-9214-4d40-bd51-da645ea1e972' | System           | 05 Aug 2020 16:05:06 |
| User entered 'No (N)'   | System           | 05 Aug 2020 16:05:06 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-05T12:05:02', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '37150400-9214-4d40-bd51-da645ea1e972' | System           | 05 Aug 2020 16:05:06 |
| User entered '05 Aug 2020 12:05'  | System           | 05 Aug 2020 16:05:06 |

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:26:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '05 Aug 2020 12:00' | System           | 01 Aug 2020 14:29:27 |



US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:26:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '06 Aug 2020 11:59' | System           | 01 Aug 2020 14:29:27 |

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.   | System           | 01 Aug 2020 14:29:27 |
| User entered 'Day 6' | System           | 01 Aug 2020 14:29:27 |

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:26:34

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-06T12:28:14', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '3f4b4732-6051-4e75-b0b5-984b580e43ca' | System           | 06 Aug 2020 16:28:31 |
| User entered 'Yes (Y)'  | System           | 06 Aug 2020 16:28:31 |

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:26:34

Please record your **TEMPERATURE** in °F

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-06T12:28:22', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '3f4b4732-6051-4e75-b0b5-984b580e43ca' User entered '97.3' | System           | 06 Aug 2020 16:28:31 |
|   | System           | 06 Aug 2020 16:28:31 |

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:26:34

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

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-06T12:28:24', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '3f4b4732-6051-4e75-b0b5-984b580e43ca' | System           | 06 Aug 2020 16:28:31 |
| User entered 'No (N)'   | System           | 06 Aug 2020 16:28:31 |

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:26:34

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-06T12:28:28', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '3f4b4732-6051-4e75-b0b5-984b580e43ca' | System           | 06 Aug 2020 16:28:31 |
| User entered '06 Aug 2020 12:28'  | System           | 06 Aug 2020 16:28:31 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '06 Aug 2020 12:00' | System           | 01 Aug 2020 14:29:27 |

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:26:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '07 Aug 2020 11:59' | System           | 01 Aug 2020 14:29:27 |



US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.   | System           | 01 Aug 2020 14:29:27 |
| User entered 'Day 7' | System           | 01 Aug 2020 14:29:27 |

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:26:34

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-07T13:02:21', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '31762feb-e5e1-4667-82d1-b0a3b587e1d7' | System           | 07 Aug 2020 17:02:34 |
| User entered 'Yes (Y)'  | System           | 07 Aug 2020 17:02:34 |

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:26:34

Please record your **TEMPERATURE** in °F

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-07T13:02:25', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '31762feb-e5e1-4667-82d1-b0a3b587e1d7' | System           | 07 Aug 2020 17:02:34 |
| User entered '98.4'   | System           | 07 Aug 2020 17:02:34 |

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:26:34

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

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-07T13:02:28', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '31762feb-e5e1-4667-82d1-b0a3b587e1d7' | System           | 07 Aug 2020 17:02:34 |
| User entered 'No (N)'   | System           | 07 Aug 2020 17:02:34 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-07T13:02:30', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '31762feb-e5e1-4667-82d1-b0a3b587e1d7' | System           | 07 Aug 2020 17:02:34 |
| User entered '07 Aug 2020 13:02'  | System           | 07 Aug 2020 17:02:34 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '07 Aug 2020 12:00' | System           | 01 Aug 2020 14:29:27 |

US3402139

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:26:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '08 Aug 2020 11:59' | System           | 01 Aug 2020 14:29:27 |

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.   | System           | 01 Aug 2020 14:29:27 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 01 Aug 2020 14:29:27 |



US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T10:59:11', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b4dac4b9-d355-4239-9d1c-ae7ea342345d' | System           | 01 Aug 2020 14:59:37 |
| User entered 'None (1)'   | System           | 01 Aug 2020 14:59:37 |

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

Is there any REDNESS AT INJECTION SITE?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T10:59:18', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b4dac4b9-d355-4239-9d1c-ae7ea342345d' | System           | 01 Aug 2020 14:59:37 |
| User entered 'No (N)'   | System           | 01 Aug 2020 14:59:37 |

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

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

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T10:59:24', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b4dac4b9-d355-4239-9d1c-ae7ea342345d' | System           | 01 Aug 2020 14:59:37 |
| User entered 'No (N)'   | System           | 01 Aug 2020 14:59:37 |

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T10:59:31', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b4dac4b9-d355-4239-9d1c-ae7ea342345d' | System           | 01 Aug 2020 14:59:37 |
| User entered 'None (1)'   | System           | 01 Aug 2020 14:59:37 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T10:59:34', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b4dac4b9-d355-4239-9d1c-ae7ea342345d' | System           | 01 Aug 2020 14:59:37 |
| User entered '01 Aug 2020 10:59'  | System           | 01 Aug 2020 14:59:37 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '01 Aug 2020 10:45' | System           | 01 Aug 2020 14:29:27 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '01 Aug 2020 13:15' | System           | 01 Aug 2020 14:29:27 |

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.                                | System           | 01 Aug 2020 14:29:27 |
| User entered 'Day 1, after vaccination (at home)' | System           | 01 Aug 2020 14:29:27 |



US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T20:37:55', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b5563a88-46b6-4fce-b761-d5de2853cb6a' | System           | 02 Aug 2020 00:38:12 |
| User entered 'None (1)'   | System           | 02 Aug 2020 00:38:12 |

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

Is there any REDNESS AT INJECTION SITE?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T20:37:59', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b5563a88-46b6-4fce-b761-d5de2853cb6a' | System           | 02 Aug 2020 00:38:12 |
| User entered 'No (N)'   | System           | 02 Aug 2020 00:38:12 |

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

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

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T20:38:02', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b5563a88-46b6-4fce-b761-d5de2853cb6a' | System           | 02 Aug 2020 00:38:12 |
| User entered 'No (N)'   | System           | 02 Aug 2020 00:38:12 |

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T20:38:05', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b5563a88-46b6-4fce-b761-d5de2853cb6a' | System           | 02 Aug 2020 00:38:12 |
| User entered 'None (1)'   | System           | 02 Aug 2020 00:38:12 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T20:38:07', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b5563a88-46b6-4fce-b761-d5de2853cb6a' | System           | 02 Aug 2020 00:38:12 |
| User entered '01 Aug 2020 20:38'  | System           | 02 Aug 2020 00:38:12 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '01 Aug 2020 14:10' | System           | 01 Aug 2020 14:29:27 |

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '02 Aug 2020 11:59' | System           | 01 Aug 2020 14:29:27 |

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.   | System           | 01 Aug 2020 14:29:27 |
| User entered 'Day 2' | System           | 01 Aug 2020 14:29:27 |



US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-02T12:01:04', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'c6b97058-d685-4251-a958-0bf2d4c7c5d1' | System           | 02 Aug 2020 16:01:23 |
| User entered 'Does not interfere with activity (2)'   | System           | 02 Aug 2020 16:01:23 |

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:26:34

Is there any REDNESS AT INJECTION SITE?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-02T12:01:07', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'c6b97058-d685-4251-a958-0bf2d4c7c5d1' | System           | 02 Aug 2020 16:01:23 |
| User entered 'No (N)'   | System           | 02 Aug 2020 16:01:23 |

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:26:34

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

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-02T12:01:13', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'c6b97058-d685-4251-a958-0bf2d4c7c5d1' | System           | 02 Aug 2020 16:01:23 |
| User entered 'No (N)'   | System           | 02 Aug 2020 16:01:23 |

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-02T12:01:18', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'c6b97058-d685-4251-a958-0bf2d4c7c5d1' | System           | 02 Aug 2020 16:01:23 |
| User entered 'None (1)'   | System           | 02 Aug 2020 16:01:23 |

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:26:34

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-02T12:01:21', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'c6b97058-d685-4251-a958-0bf2d4c7c5d1' | System           | 02 Aug 2020 16:01:23 |
| User entered '02 Aug 2020 12:01'  | System           | 02 Aug 2020 16:01:23 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '02 Aug 2020 12:00' | System           | 01 Aug 2020 14:29:27 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '03 Aug 2020 11:59' | System           | 01 Aug 2020 14:29:27 |

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.   | System           | 01 Aug 2020 14:29:27 |
| User entered 'Day 3' | System           | 01 Aug 2020 14:29:27 |



US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-03T12:35:57', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'f436026b-92cf-42c2-b753-ea26dab39b15' | System           | 03 Aug 2020 16:36:30 |
| User entered 'None (1)'   | System           | 03 Aug 2020 16:36:30 |

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:26:34

Is there any REDNESS AT INJECTION SITE?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-03T12:35:59', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'f436026b-92cf-42c2-b753-ea26dab39b15' | System           | 03 Aug 2020 16:36:30 |
| User entered 'No (N)'   | System           | 03 Aug 2020 16:36:30 |

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:26:34

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

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-03T12:36:02', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'f436026b-92cf-42c2-b753-ea26dab39b15' | System           | 03 Aug 2020 16:36:30 |
| User entered 'No (N)'   | System           | 03 Aug 2020 16:36:30 |

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-03T12:36:22', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'f436026b-92cf-42c2-b753-ea26dab39b15' | System           | 03 Aug 2020 16:36:30 |
| User entered 'None (1)'   | System           | 03 Aug 2020 16:36:30 |

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:26:34

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-03T12:36:26', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'f436026b-92cf-42c2-b753-ea26dab39b15' | System           | 03 Aug 2020 16:36:30 |
| User entered '03 Aug 2020 12:36'  | System           | 03 Aug 2020 16:36:30 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '03 Aug 2020 12:00' | System           | 01 Aug 2020 14:29:27 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '04 Aug 2020 11:59' | System           | 01 Aug 2020 14:29:27 |

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.   | System           | 01 Aug 2020 14:29:27 |
| User entered 'Day 4' | System           | 01 Aug 2020 14:29:27 |



US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-04T12:02:16', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'c068ccce-b121-41bf-bb7e-372940a8df0e' | System           | 04 Aug 2020 16:02:30 |
| User entered 'None (1)'   | System           | 04 Aug 2020 16:02:30 |

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:26:34

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

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-04T12:02:19', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'c068ccce-b121-41bf-bb7e-372940a8df0e' | System           | 04 Aug 2020 16:02:30 |
| User entered 'No (N)'   | System           | 04 Aug 2020 16:02:30 |

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:26:34

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

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-04T12:02:23', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'c068ccce-b121-41bf-bb7e-372940a8df0e' | System           | 04 Aug 2020 16:02:30 |
| User entered 'No (N)'   | System           | 04 Aug 2020 16:02:30 |

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-04T12:02:25', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'c068ccce-b121-41bf-bb7e-372940a8df0e' | System           | 04 Aug 2020 16:02:30 |
| User entered 'None (1)'   | System           | 04 Aug 2020 16:02:30 |

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:26:34

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-04T12:02:27', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'c068ccce-b121-41bf-bb7e-372940a8df0e' | System           | 04 Aug 2020 16:02:30 |
| User entered '04 Aug 2020 12:02'  | System           | 04 Aug 2020 16:02:30 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '04 Aug 2020 12:00' | System           | 01 Aug 2020 14:29:27 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '05 Aug 2020 11:59' | System           | 01 Aug 2020 14:29:27 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.   | System           | 01 Aug 2020 14:29:27 |
| User entered 'Day 5' | System           | 01 Aug 2020 14:29:27 |



US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-05T12:05:06', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '479b3763-84ac-41f3-a658-1a5be329eb01' | System           | 05 Aug 2020 16:05:21 |
| User entered 'None (1)'   | System           | 05 Aug 2020 16:05:21 |

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:26:34

Is there any REDNESS AT INJECTION SITE?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-05T12:05:10', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '479b3763-84ac-41f3-a658-1a5be329eb01' | System           | 05 Aug 2020 16:05:21 |
| User entered 'No (N)'   | System           | 05 Aug 2020 16:05:21 |

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:26:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-05T12:05:13', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '479b3763-84ac-41f3-a658-1a5be329eb01' | System           | 05 Aug 2020 16:05:21 |
| User entered 'No (N)'   | System           | 05 Aug 2020 16:05:21 |

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-05T12:05:16', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '479b3763-84ac-41f3-a658-1a5be329eb01' | System           | 05 Aug 2020 16:05:21 |
| User entered 'None (1)'   | System           | 05 Aug 2020 16:05:21 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-05T12:05:18', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '479b3763-84ac-41f3-a658-1a5be329eb01' | System           | 05 Aug 2020 16:05:21 |
| User entered '05 Aug 2020 12:05'  | System           | 05 Aug 2020 16:05:21 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '05 Aug 2020 12:00' | System           | 01 Aug 2020 14:29:27 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '06 Aug 2020 11:59' | System           | 01 Aug 2020 14:29:27 |

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.   | System           | 01 Aug 2020 14:29:27 |
| User entered 'Day 6' | System           | 01 Aug 2020 14:29:27 |



US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-06T12:28:31', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '5e84def8-7c99-482d-b8e7-c4716fd01518' | System           | 06 Aug 2020 16:28:43 |
| User entered 'None (1)'   | System           | 06 Aug 2020 16:28:43 |

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:26:34

Is there any REDNESS AT INJECTION SITE?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-06T12:28:33', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '5e84def8-7c99-482d-b8e7-c4716fd01518' | System           | 06 Aug 2020 16:28:43 |
| User entered 'No (N)'   | System           | 06 Aug 2020 16:28:43 |

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:26:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-06T12:28:35', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '5e84def8-7c99-482d-b8e7-c4716fd01518' | System           | 06 Aug 2020 16:28:43 |
| User entered 'No (N)'   | System           | 06 Aug 2020 16:28:43 |

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-06T12:28:37', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '5e84def8-7c99-482d-b8e7-c4716fd01518' | System           | 06 Aug 2020 16:28:43 |
| User entered 'None (1)'   | System           | 06 Aug 2020 16:28:43 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-06T12:28:38', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '5e84def8-7c99-482d-b8e7-c4716fd01518' | System           | 06 Aug 2020 16:28:43 |
| User entered '06 Aug 2020 12:28'  | System           | 06 Aug 2020 16:28:43 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '06 Aug 2020 12:00' | System           | 01 Aug 2020 14:29:27 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '07 Aug 2020 11:59' | System           | 01 Aug 2020 14:29:27 |

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.   | System           | 01 Aug 2020 14:29:27 |
| User entered 'Day 7' | System           | 01 Aug 2020 14:29:27 |



US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-07T13:02:34', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'a78afc74-76e6-474b-b62b-6f0cb5d8d70c' | System           | 07 Aug 2020 17:02:43 |
| User entered 'None (1)'   | System           | 07 Aug 2020 17:02:43 |

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:26:34

Is there any **REDNESS AT INJECTION SITE?**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-07T13:02:36', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'a78afc74-76e6-474b-b62b-6f0cb5d8d70c' | System           | 07 Aug 2020 17:02:43 |
| User entered 'No (N)'   | System           | 07 Aug 2020 17:02:43 |

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:26:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-07T13:02:37', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'a78afc74-76e6-474b-b62b-6f0cb5d8d70c' | System           | 07 Aug 2020 17:02:43 |
| User entered 'No (N)'   | System           | 07 Aug 2020 17:02:43 |

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-07T13:02:39', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'a78afc74-76e6-474b-b62b-6f0cb5d8d70c' | System           | 07 Aug 2020 17:02:43 |
| User entered 'None (1)'   | System           | 07 Aug 2020 17:02:43 |

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:26:34

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-07T13:02:41', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'a78afc74-76e6-474b-b62b-6f0cb5d8d70c' | System           | 07 Aug 2020 17:02:43 |
| User entered '07 Aug 2020 13:02'  | System           | 07 Aug 2020 17:02:43 |

US3402139

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:26:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '07 Aug 2020 12:00' | System           | 01 Aug 2020 14:29:27 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '08 Aug 2020 11:59' | System           | 01 Aug 2020 14:29:27 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.   | System           | 01 Aug 2020 14:29:27 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 01 Aug 2020 14:29:27 |



US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

**HEADACHE**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T10:59:41', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b9df7cf2-3282-4bc7-a87f-372f5154ff00' | System           | 01 Aug 2020 15:00:19 |
| User entered 'None (0)'   | System           | 01 Aug 2020 15:00:19 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

**FATIGUE**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T11:00:00', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b9df7cf2-3282-4bc7-a87f-372f5154ff00' | System           | 01 Aug 2020 15:00:19 |
| User entered 'None (0)'   | System           | 01 Aug 2020 15:00:19 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

**MUSCLE ACHES ALL OVER BODY**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T11:00:02', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b9df7cf2-3282-4bc7-a87f-372f5154ff00' | System           | 01 Aug 2020 15:00:19 |
| User entered 'None (0)'   | System           | 01 Aug 2020 15:00:19 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

**JOINT ACHES IN SEVERAL JOINTS**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T11:00:05', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b9df7cf2-3282-4bc7-a87f-372f5154ff00' | System           | 01 Aug 2020 15:00:19 |
| User entered 'None (0)'   | System           | 01 Aug 2020 15:00:19 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

**NAUSEA/VOMITING**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T11:00:07', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b9df7cf2-3282-4bc7-a87f-372f5154ff00' | System           | 01 Aug 2020 15:00:19 |
| User entered 'None (0)'   | System           | 01 Aug 2020 15:00:19 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

**CHILLS**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T11:00:09', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b9df7cf2-3282-4bc7-a87f-372f5154ff00' | System           | 01 Aug 2020 15:00:19 |
| User entered 'None (0)'   | System           | 01 Aug 2020 15:00:19 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T11:00:12', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b9df7cf2-3282-4bc7-a87f-372f5154ff00' | System           | 01 Aug 2020 15:00:19 |
| User entered 'No (N)'   | System           | 01 Aug 2020 15:00:19 |

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Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T11:00:15', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b9df7cf2-3282-4bc7-a87f-372f5154ff00' | System           | 01 Aug 2020 15:00:19 |
| User entered '01 Aug 2020 11:00'  | System           | 01 Aug 2020 15:00:19 |



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Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '01 Aug 2020 10:45' | System           | 01 Aug 2020 14:29:27 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '01 Aug 2020 13:15' | System           | 01 Aug 2020 14:29:27 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.                                | System           | 01 Aug 2020 14:29:27 |
| User entered 'Day 1, after vaccination (at home)' | System           | 01 Aug 2020 14:29:27 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

**HEADACHE**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T20:38:13', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '1d06e0a1-4aef-4ad7-887a-5d7a080e1655' | System           | 02 Aug 2020 00:38:37 |
| User entered 'None (0)'   | System           | 02 Aug 2020 00:38:37 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

**FATIGUE**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T20:38:16', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '1d06e0a1-4aef-4ad7-887a-5d7a080e1655' | System           | 02 Aug 2020 00:38:37 |
| User entered 'None (0)'   | System           | 02 Aug 2020 00:38:37 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

**MUSCLE ACHES ALL OVER BODY**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T20:38:19', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '1d06e0a1-4aef-4ad7-887a-5d7a080e1655' | System           | 02 Aug 2020 00:38:37 |
| User entered 'None (0)'   | System           | 02 Aug 2020 00:38:37 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

**JOINT ACHES IN SEVERAL JOINTS**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T20:38:22', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '1d06e0a1-4aef-4ad7-887a-5d7a080e1655' | System           | 02 Aug 2020 00:38:37 |
| User entered 'None (0)'   | System           | 02 Aug 2020 00:38:37 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

**NAUSEA/VOMITING**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T20:38:24', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '1d06e0a1-4aef-4ad7-887a-5d7a080e1655' | System           | 02 Aug 2020 00:38:37 |
| User entered 'None (0)'   | System           | 02 Aug 2020 00:38:37 |



US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

**CHILLS**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T20:38:27', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '1d06e0a1-4aef-4ad7-887a-5d7a080e1655' | System           | 02 Aug 2020 00:38:37 |
| User entered 'None (0)'   | System           | 02 Aug 2020 00:38:37 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T20:38:31', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '1d06e0a1-4aef-4ad7-887a-5d7a080e1655' | System           | 02 Aug 2020 00:38:37 |
| User entered 'No (N)'   | System           | 02 Aug 2020 00:38:37 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-01T20:38:33', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '1d06e0a1-4aef-4ad7-887a-5d7a080e1655' | System           | 02 Aug 2020 00:38:37 |
| User entered '01 Aug 2020 20:38'  | System           | 02 Aug 2020 00:38:37 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '01 Aug 2020 14:10' | System           | 01 Aug 2020 14:29:27 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '02 Aug 2020 11:59' | System           | 01 Aug 2020 14:29:27 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.   | System           | 01 Aug 2020 14:29:27 |
| User entered 'Day 2' | System           | 01 Aug 2020 14:29:27 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:26:34

**HEADACHE**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-02T12:01:28', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '0832cbaa-de2a-4488-a6ea-28f49ca61041' | System           | 02 Aug 2020 16:01:47 |
| User entered 'None (0)'   | System           | 02 Aug 2020 16:01:47 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:26:34

**FATIGUE**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-02T12:01:31', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '0832cbaa-de2a-4488-a6ea-28f49ca61041' | System           | 02 Aug 2020 16:01:47 |
| User entered 'None (0)'   | System           | 02 Aug 2020 16:01:47 |



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Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:26:34

**MUSCLE ACHES ALL OVER BODY**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-02T12:01:33', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '0832cbaa-de2a-4488-a6ea-28f49ca61041' | System           | 02 Aug 2020 16:01:47 |
| User entered 'None (0)'   | System           | 02 Aug 2020 16:01:47 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:26:34

**JOINT ACHES IN SEVERAL JOINTS**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-02T12:01:36', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '0832cbaa-de2a-4488-a6ea-28f49ca61041' | System           | 02 Aug 2020 16:01:47 |
| User entered 'None (0)'   | System           | 02 Aug 2020 16:01:47 |

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Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:26:34

**NAUSEA/VOMITING**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-02T12:01:38', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '0832cbaa-de2a-4488-a6ea-28f49ca61041' | System           | 02 Aug 2020 16:01:47 |
| User entered 'None (0)'   | System           | 02 Aug 2020 16:01:47 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:26:34

**CHILLS**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-02T12:01:40', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '0832cbaa-de2a-4488-a6ea-28f49ca61041' | System           | 02 Aug 2020 16:01:47 |
| User entered 'None (0)'   | System           | 02 Aug 2020 16:01:47 |

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Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-02T12:01:42', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '0832cbaa-de2a-4488-a6ea-28f49ca61041' | System           | 02 Aug 2020 16:01:47 |
| User entered 'No (N)'   | System           | 02 Aug 2020 16:01:47 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:26:34

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-02T12:01:45', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '0832cbaa-de2a-4488-a6ea-28f49ca61041' | System           | 02 Aug 2020 16:01:47 |
| User entered '02 Aug 2020 12:01'  | System           | 02 Aug 2020 16:01:47 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '02 Aug 2020 12:00' | System           | 01 Aug 2020 14:29:27 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '03 Aug 2020 11:59' | System           | 01 Aug 2020 14:29:27 |



**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.   | System           | 01 Aug 2020 14:29:27 |
| User entered 'Day 3' | System           | 01 Aug 2020 14:29:27 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:26:34

**HEADACHE**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-03T12:36:29', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '8143c872-d2d2-43db-be4b-23edee9aace4' | System           | 03 Aug 2020 16:36:49 |
| User entered 'None (0)'   | System           | 03 Aug 2020 16:36:49 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:26:34

**FATIGUE**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-03T12:36:31', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '8143c872-d2d2-43db-be4b-23edee9aace4' | System           | 03 Aug 2020 16:36:49 |
| User entered 'None (0)'   | System           | 03 Aug 2020 16:36:49 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:26:34

**MUSCLE ACHES ALL OVER BODY**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-03T12:36:33', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '8143c872-d2d2-43db-be4b-23edee9aace4' | System           | 03 Aug 2020 16:36:49 |
| User entered 'None (0)'   | System           | 03 Aug 2020 16:36:49 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:26:34

**JOINT ACHES IN SEVERAL JOINTS**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-03T12:36:35', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '8143c872-d2d2-43db-be4b-23edee9aace4' | System           | 03 Aug 2020 16:36:49 |
| User entered 'None (0)'   | System           | 03 Aug 2020 16:36:49 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:26:34

**NAUSEA/VOMITING**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-03T12:36:37', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '8143c872-d2d2-43db-be4b-23edee9aace4' | System           | 03 Aug 2020 16:36:49 |
| User entered 'None (0)'   | System           | 03 Aug 2020 16:36:49 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:26:34

**CHILLS**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-03T12:36:39', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '8143c872-d2d2-43db-be4b-23edee9aace4' | System           | 03 Aug 2020 16:36:49 |
| User entered 'None (0)'   | System           | 03 Aug 2020 16:36:49 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-03T12:36:42', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '8143c872-d2d2-43db-be4b-23edee9aace4' | System           | 03 Aug 2020 16:36:49 |
| User entered 'No (N)'   | System           | 03 Aug 2020 16:36:49 |



**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-03T12:36:44', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '8143c872-d2d2-43db-be4b-23edee9aace4' | System           | 03 Aug 2020 16:36:49 |
| User entered '03 Aug 2020 12:36'  | System           | 03 Aug 2020 16:36:49 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '03 Aug 2020 12:00' | System           | 01 Aug 2020 14:29:27 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '04 Aug 2020 11:59' | System           | 01 Aug 2020 14:29:27 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.   | System           | 01 Aug 2020 14:29:27 |
| User entered 'Day 4' | System           | 01 Aug 2020 14:29:27 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:26:34

**HEADACHE**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-04T12:02:31', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '4a972e63-17ee-4840-9e21-f01d69647974' | System           | 04 Aug 2020 16:02:59 |
| User entered 'None (0)'   | System           | 04 Aug 2020 16:02:59 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:26:34

**FATIGUE**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-04T12:02:33', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '4a972e63-17ee-4840-9e21-f01d69647974' | System           | 04 Aug 2020 16:02:59 |
| User entered 'None (0)'   | System           | 04 Aug 2020 16:02:59 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:26:34

**MUSCLE ACHES ALL OVER BODY**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-04T12:02:35', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '4a972e63-17ee-4840-9e21-f01d69647974' | System           | 04 Aug 2020 16:02:59 |
| User entered 'None (0)'   | System           | 04 Aug 2020 16:02:59 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:26:34

**JOINT ACHES IN SEVERAL JOINTS**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-04T12:02:37', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '4a972e63-17ee-4840-9e21-f01d69647974' | System           | 04 Aug 2020 16:02:59 |
| User entered 'None (0)'   | System           | 04 Aug 2020 16:02:59 |



US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:26:34

**NAUSEA/VOMITING**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-04T12:02:39', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '4a972e63-17ee-4840-9e21-f01d69647974' | System           | 04 Aug 2020 16:02:59 |
| User entered 'None (0)'   | System           | 04 Aug 2020 16:02:59 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:26:34

**CHILLS**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-04T12:02:41', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '4a972e63-17ee-4840-9e21-f01d69647974' | System           | 04 Aug 2020 16:02:59 |
| User entered 'None (0)'   | System           | 04 Aug 2020 16:02:59 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-04T12:02:44', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '4a972e63-17ee-4840-9e21-f01d69647974' | System           | 04 Aug 2020 16:02:59 |
| User entered 'No (N)'   | System           | 04 Aug 2020 16:02:59 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-04T12:02:55', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '4a972e63-17ee-4840-9e21-f01d69647974' | System           | 04 Aug 2020 16:02:59 |
| User entered '04 Aug 2020 12:02'  | System           | 04 Aug 2020 16:02:59 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '04 Aug 2020 12:00' | System           | 01 Aug 2020 14:29:27 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '05 Aug 2020 11:59' | System           | 01 Aug 2020 14:29:27 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.   | System           | 01 Aug 2020 14:29:27 |
| User entered 'Day 5' | System           | 01 Aug 2020 14:29:27 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:26:34

**HEADACHE**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-05T12:05:22', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '78d6207e-f8a2-4554-802f-8d5fcc4110d1' | System           | 05 Aug 2020 16:05:37 |
| User entered 'None (0)'   | System           | 05 Aug 2020 16:05:37 |



US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:26:34

**FATIGUE**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-05T12:05:23', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '78d6207e-f8a2-4554-802f-8d5fcc4110d1' | System           | 05 Aug 2020 16:05:37 |
| User entered 'None (0)'   | System           | 05 Aug 2020 16:05:37 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:26:34

**MUSCLE ACHES ALL OVER BODY**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-05T12:05:25', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '78d6207e-f8a2-4554-802f-8d5fcc4110d1' | System           | 05 Aug 2020 16:05:37 |
| User entered 'None (0)'   | System           | 05 Aug 2020 16:05:37 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:26:34

**JOINT ACHES IN SEVERAL JOINTS**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-05T12:05:27', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '78d6207e-f8a2-4554-802f-8d5fcc4110d1' | System           | 05 Aug 2020 16:05:37 |
| User entered 'None (0)'   | System           | 05 Aug 2020 16:05:37 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:26:34

**NAUSEA/VOMITING**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-05T12:05:29', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '78d6207e-f8a2-4554-802f-8d5fcc4110d1' | System           | 05 Aug 2020 16:05:37 |
| User entered 'None (0)'   | System           | 05 Aug 2020 16:05:37 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:26:34**

**CHILLS**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-05T12:05:31', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '78d6207e-f8a2-4554-802f-8d5fcc4110d1' | System           | 05 Aug 2020 16:05:37 |
| User entered 'None (0)'   | System           | 05 Aug 2020 16:05:37 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-05T12:05:33', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '78d6207e-f8a2-4554-802f-8d5fcc4110d1' | System           | 05 Aug 2020 16:05:37 |
| User entered 'No (N)'   | System           | 05 Aug 2020 16:05:37 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-05T12:05:35', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '78d6207e-f8a2-4554-802f-8d5fcc4110d1' | System           | 05 Aug 2020 16:05:37 |
| User entered '05 Aug 2020 12:05'  | System           | 05 Aug 2020 16:05:37 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '05 Aug 2020 12:00' | System           | 01 Aug 2020 14:29:27 |



**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '06 Aug 2020 11:59' | System           | 01 Aug 2020 14:29:27 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.   | System           | 01 Aug 2020 14:29:27 |
| User entered 'Day 6' | System           | 01 Aug 2020 14:29:27 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:26:34

**HEADACHE**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-06T12:28:42', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '5a1660b3-9112-4d4a-9baa-ee8edb66b7a3' | System           | 06 Aug 2020 16:29:01 |
| User entered 'None (0)'   | System           | 06 Aug 2020 16:29:01 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:26:34

**FATIGUE**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-06T12:28:45', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '5a1660b3-9112-4d4a-9baa-ee8edb66b7a3' | System           | 06 Aug 2020 16:29:01 |
| User entered 'None (0)'   | System           | 06 Aug 2020 16:29:01 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:26:34

**MUSCLE ACHES ALL OVER BODY**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-06T12:28:46', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '5a1660b3-9112-4d4a-9baa-ee8edb66b7a3' | System           | 06 Aug 2020 16:29:01 |
| User entered 'None (0)'   | System           | 06 Aug 2020 16:29:01 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:26:34

**JOINT ACHES IN SEVERAL JOINTS**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-06T12:28:49', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '5a1660b3-9112-4d4a-9baa-ee8edb66b7a3' User entered 'None (0)' | System           | 06 Aug 2020 16:29:01 |
|   | System           | 06 Aug 2020 16:29:01 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:26:34

**NAUSEA/VOMITING**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-06T12:28:50', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '5a1660b3-9112-4d4a-9baa-ee8edb66b7a3' | System           | 06 Aug 2020 16:29:01 |
| User entered 'None (0)'   | System           | 06 Aug 2020 16:29:01 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:26:34

**CHILLS**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-06T12:28:52', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '5a1660b3-9112-4d4a-9baa-ee8edb66b7a3' | System           | 06 Aug 2020 16:29:01 |
| User entered 'None (0)'   | System           | 06 Aug 2020 16:29:01 |



US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-06T12:28:54', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '5a1660b3-9112-4d4a-9baa-ee8edb66b7a3' | System           | 06 Aug 2020 16:29:01 |
| User entered 'No (N)'   | System           | 06 Aug 2020 16:29:01 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-06T12:28:56', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '5a1660b3-9112-4d4a-9baa-ee8edb66b7a3' | System           | 06 Aug 2020 16:29:01 |
| User entered '06 Aug 2020 12:28'  | System           | 06 Aug 2020 16:29:01 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '06 Aug 2020 12:00' | System           | 01 Aug 2020 14:29:27 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '07 Aug 2020 11:59' | System           | 01 Aug 2020 14:29:27 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.   | System           | 01 Aug 2020 14:29:27 |
| User entered 'Day 7' | System           | 01 Aug 2020 14:29:27 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:26:34

**HEADACHE**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-07T13:02:45', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'fa432eb8-1ca5-4295-8722-703f0bd9096f' User entered 'None (0)' | System           | 07 Aug 2020 17:03:01 |
|   | System           | 07 Aug 2020 17:03:01 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:26:34

**FATIGUE**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-07T13:02:47', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'fa432eb8-1ca5-4295-8722-703f0bd9096f' User entered 'None (0)' | System           | 07 Aug 2020 17:03:01 |
|   | System           | 07 Aug 2020 17:03:01 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:26:34

**MUSCLE ACHES ALL OVER BODY**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-07T13:02:49', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'fa432eb8-1ca5-4295-8722-703f0bd9096f' User entered 'None (0)' | System           | 07 Aug 2020 17:03:01 |
|   | System           | 07 Aug 2020 17:03:01 |



US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:26:34

**JOINT ACHES IN SEVERAL JOINTS**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-07T13:02:50', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'fa432eb8-1ca5-4295-8722-703f0bd9096f' User entered 'None (0)' | System           | 07 Aug 2020 17:03:01 |
|   | System           | 07 Aug 2020 17:03:01 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:26:34

**NAUSEA/VOMITING**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-07T13:02:52', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'fa432eb8-1ca5-4295-8722-703f0bd9096f' User entered 'None (0)' | System           | 07 Aug 2020 17:03:01 |
|   | System           | 07 Aug 2020 17:03:01 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:26:34

**CHILLS**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-07T13:02:53', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'fa432eb8-1ca5-4295-8722-703f0bd9096f' User entered 'None (0)' | System           | 07 Aug 2020 17:03:01 |
|   | System           | 07 Aug 2020 17:03:01 |

US3402139

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-07T13:02:56', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'fa432eb8-1ca5-4295-8722-703f0bd9096f' User entered 'No (N)' | System           | 07 Aug 2020 17:03:01 |
|   | System           | 07 Aug 2020 17:03:01 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-07T13:02:57', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'fa432eb8-1ca5-4295-8722-703f0bd9096f' | System           | 07 Aug 2020 17:03:01 |
| User entered '07 Aug 2020 13:02'  | System           | 07 Aug 2020 17:03:01 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '07 Aug 2020 12:00' | System           | 01 Aug 2020 14:29:27 |

**US3402139**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '08 Aug 2020 11:59' | System           | 01 Aug 2020 14:29:27 |

**US3402139**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

[Was Contact Attempted?](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                         | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)                       | 15 Feb 2021 16:53:16 |
| User entered 'Yes (Y)'    | (b) (4)<br>Traci Hull (b) (4)<br>(b) (4) | 10 Aug 2020 12:38:25 |



**US3402139**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit   | User               | Time (GMT)           |
|---|--------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded.                                     | Frank Eder (b) (4) | 15 Feb 2021 16:53:16 |
| User entered '08 Aug 2020' reason for change: New Information | Traci Hull (b) (4) | 11 Nov 2020 12:30:58 |
| User entered '8 Aug 2020'                                     | Traci Hull (b) (4) | 10 Aug 2020 12:38:25 |

**US3402139**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

[Please select one status for the follow-up contact](#)

| Audit                                      | User               | Time (GMT)           |
|--|--------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded.                  | Frank Eder (b) (4) | 15 Feb 2021 16:53:16 |
| User entered 'Contact Made (CONTACT MADE)' | Traci Hull (b) (4) | 10 Aug 2020 12:38:25 |

**US3402139**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 16:53:16 |
| User entered empty.       | Traci Hull (b) (4) | 10 Aug 2020 12:38:25 |

**US3402139**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:26:34**

[Is the participant continuing to the next visit?](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 16:53:16 |
| User entered 'Yes (Y)'    | Traci Hull (b) (4) | 10 Aug 2020 12:38:31 |

**US3402139**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:26:34**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered 'I'  | System           | 10 Aug 2020 12:38:31 |

**US3402139**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

[Was Contact Attempted?](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)              | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)            | 15 Feb 2021 16:53:16 |
| User entered 'Yes (Y)'    | (b) (4)<br>Traci Hull (b) (4) | 24 Aug 2020 21:37:08 |

**US3402139**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                      | User               | Time (GMT)           |
|----------------------------|--------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded.  | Frank Eder (b) (4) | 15 Feb 2021 16:53:16 |
| User entered '15 Aug 2020' | Traci Hull (b) (4) | 24 Aug 2020 21:37:08 |

**US3402139**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

[Please select one status for the follow-up contact](#)

| Audit                                      | User               | Time (GMT)           |
|--|--------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded.                  | Frank Eder (b) (4) | 15 Feb 2021 16:53:16 |
| User entered 'Contact Made (CONTACT MADE)' | Traci Hull (b) (4) | 24 Aug 2020 21:37:08 |



**US3402139**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 16:53:16 |
| User entered empty.       | Traci Hull (b) (4) | 24 Aug 2020 21:37:08 |

**US3402139**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:26:34**

[Is the participant continuing to the next visit?](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 16:53:16 |
| User entered 'Yes (Y)'    | Traci Hull (b) (4) | 24 Aug 2020 21:37:14 |

**US3402139**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:26:34**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered 'I'  | System           | 24 Aug 2020 21:37:14 |

**US3402139**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

[Was Contact Attempted?](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                         | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)                       | 15 Feb 2021 16:53:16 |
| User entered 'Yes (Y)'    | (b) (4)<br>Traci Hull (b) (4)<br>(b) (4) | 24 Aug 2020 21:37:29 |

**US3402139**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                      | User               | Time (GMT)           |
|----------------------------|--------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded.  | Frank Eder (b) (4) | 15 Feb 2021 16:53:16 |
| User entered '22 Aug 2020' | Traci Hull (b) (4) | 24 Aug 2020 21:37:29 |

**US3402139**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

[Please select one status for the follow-up contact](#)

| Audit                                      | User               | Time (GMT)           |
|--|--------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded.                  | Frank Eder (b) (4) | 15 Feb 2021 16:53:16 |
| User entered 'Contact Made (CONTACT MADE)' | Traci Hull (b) (4) | 24 Aug 2020 21:37:29 |

**US3402139**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 16:53:16 |
| User entered empty.       | Traci Hull (b) (4) | 24 Aug 2020 21:37:29 |

**US3402139**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:26:34**

[Is the participant continuing to the next visit?](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 16:53:16 |
| User entered 'Yes (Y)'    | Traci Hull (b) (4) | 24 Aug 2020 21:37:37 |



**US3402139**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:26:34**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered 'I'  | System           | 24 Aug 2020 21:37:37 |

**US3402139**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:26:34**

[Was this visit performed?](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                         | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)                       | 15 Feb 2021 16:53:21 |
| User entered 'Yes (Y)'    | (b) (4)<br>Traci Hull (b) (4)<br>(b) (4) | 31 Aug 2020 13:34:26 |

US3402139

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:34

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                                     | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                         | 27 Mar 2021 18:38:17 |
| User signature succeeded.  | Frank Eder (b) (4)                       | 15 Feb 2021 16:53:21 |
| User entered '31 Aug 2020' | (b) (4)<br>Traci Hull (b) (4)<br>(b) (4) | 31 Aug 2020 13:34:26 |

US3402139

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:34

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                                     | Time (GMT)           |
|--------------------------------|--|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                         | 27 Mar 2021 18:38:17 |
| User signature succeeded.      | Frank Eder (b) (4)                       | 15 Feb 2021 16:53:21 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>Traci Hull (b) (4)<br>(b) (4) | 31 Aug 2020 13:34:26 |

**US3402139**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:26:34**

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered 'VISIT2' | System           | 31 Aug 2020 13:34:26 |

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:34

[Timepoint](#)

| Audit  | User                          | Time (GMT)           |
|--|-------------------------------|----------------------|
| Data hard locked.                                | (b) (4), (b) (6)              | 27 Mar 2021 18:38:17 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Traci Hull (b) (4)<br>(b) (4) | 31 Aug 2020 13:35:48 |

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:34

[Were vital signs assessed?](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)              | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)            | 15 Feb 2021 16:53:21 |
| User entered 'Yes (Y)'    | (b) (4)<br>Traci Hull (b) (4) | 31 Aug 2020 13:35:48 |

**US3402139**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:26:34**

**Date of assessment** (*dd MMM yyyy*)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)              | 27 Mar 2021 18:38:17 |
| User signature succeeded.  | Frank Eder (b) (4)            | 15 Feb 2021 16:53:21 |
| User entered '31 Aug 2020' | (b) (4)<br>Traci Hull (b) (4) | 31 Aug 2020 13:35:48 |



**US3402139**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:26:34**

**Time of assessment (00:00-23:59)**

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 16:53:21 |
| User entered '08:14'      | Traci Hull (b) (4) | 31 Aug 2020 13:35:48 |

**US3402139**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:26:34**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered '31 Aug 2020 08:14' | System           | 31 Aug 2020 13:35:48 |

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:34

Temperature (xxx.x)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 16:53:21 |
| User entered '36.8' C     | (b) (4)            |                      |
|                           | Traci Hull (b) (4) | 31 Aug 2020 13:35:48 |
|                           | (b) (4)            |                      |

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:34

[Route of measurement](#)

| Audit                      | User                                     | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                         | 27 Mar 2021 18:38:17 |
| User signature succeeded.  | Frank Eder (b) (4)                       | 15 Feb 2021 16:53:21 |
| User entered 'Oral (Oral)' | (b) (4)<br>Traci Hull (b) (4)<br>(b) (4) | 31 Aug 2020 13:35:48 |

**US3402139**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:26:34**

[If Other, specify](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)              | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)            | 15 Feb 2021 16:53:21 |
| User entered empty.       | (b) (4)<br>Traci Hull (b) (4) | 31 Aug 2020 13:35:48 |

**US3402139**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:26:34**

[Pulse \(xxx\)](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 16:53:21 |
| User entered '63'         | Traci Hull (b) (4) | 31 Aug 2020 13:35:48 |

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:34

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered 'bpm' | System           | 31 Aug 2020 13:35:48 |

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:34

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)              | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)            | 15 Feb 2021 16:53:21 |
| User entered '14'         | (b) (4)<br>Traci Hull (b) (4) | 31 Aug 2020 13:35:48 |



US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:34

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered 'breaths/min' | System           | 31 Aug 2020 13:35:48 |

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:34

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                         | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)                       | 15 Feb 2021 16:53:21 |
| User entered '114'        | (b) (4)<br>Traci Hull (b) (4)<br>(b) (4) | 31 Aug 2020 13:35:48 |

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:34

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered 'mmHg' | System           | 31 Aug 2020 13:35:48 |

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:34

Diastolic Blood Pressure (xxx)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 16:53:21 |
| User entered '60'         | Traci Hull (b) (4) | 31 Aug 2020 13:35:48 |

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:34

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered 'mmHg' | System           | 31 Aug 2020 13:35:48 |

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:34

[Timepoint](#)

| Audit  | User                          | Time (GMT)           |
|--|-------------------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6)              | 27 Mar 2021 18:38:17 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Traci Hull (b) (4)<br>(b) (4) | 31 Aug 2020 13:35:48 |

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:34

[Were vital signs assessed?](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)              | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)            | 15 Feb 2021 16:53:21 |
| User entered 'Yes (Y)'    | (b) (4)<br>Traci Hull (b) (4) | 31 Aug 2020 13:35:48 |

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:34

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                                     | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                         | 27 Mar 2021 18:38:17 |
| User signature succeeded.  | Frank Eder (b) (4)                       | 15 Feb 2021 16:53:21 |
| User entered '31 Aug 2020' | (b) (4)<br>Traci Hull (b) (4)<br>(b) (4) | 31 Aug 2020 13:35:48 |



**US3402139**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:26:34**

**Time of assessment (00:00-23:59)**

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 16:53:21 |
| User entered '09:12'      | (b) (4)            |                      |
|                           | Traci Hull (b) (4) | 31 Aug 2020 13:35:48 |
|                           | (b) (4)            |                      |

**US3402139**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:26:34**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered '31 Aug 2020 09:12' | System           | 31 Aug 2020 13:35:48 |

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:34

Temperature (xxx.x)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 16:53:21 |
| User entered '36.8' C     | (b) (4)            |                      |
|                           | Traci Hull (b) (4) | 31 Aug 2020 13:35:48 |
|                           | (b) (4)            |                      |

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:34

[Route of measurement](#)

| Audit                      | User                                     | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                         | 27 Mar 2021 18:38:17 |
| User signature succeeded.  | Frank Eder (b) (4)                       | 15 Feb 2021 16:53:21 |
| User entered 'Oral (Oral)' | (b) (4)<br>Traci Hull (b) (4)<br>(b) (4) | 31 Aug 2020 13:35:48 |

**US3402139**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:26:34**

[If Other, specify](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)              | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)            | 15 Feb 2021 16:53:21 |
| User entered empty.       | (b) (4)<br>Traci Hull (b) (4) | 31 Aug 2020 13:35:48 |

**US3402139**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:26:34**

[Pulse \(xxx\)](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 16:53:21 |
| User entered '56'         | Traci Hull (b) (4) | 31 Aug 2020 13:35:48 |

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:34

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered 'bpm' | System           | 31 Aug 2020 13:35:48 |

US3402139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:34

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)              | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)            | 15 Feb 2021 16:53:21 |
| User entered '14'         | (b) (4)<br>Traci Hull (b) (4) | 31 Aug 2020 13:35:48 |



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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:34

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered 'breaths/min' | System           | 31 Aug 2020 13:35:48 |

**US3402139**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:26:34**

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                         | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)                       | 15 Feb 2021 16:53:21 |
| User entered '118'        | (b) (4)<br>Traci Hull (b) (4)<br>(b) (4) | 31 Aug 2020 13:35:48 |

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:34

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered 'mmHg' | System           | 31 Aug 2020 13:35:48 |

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:34

Diastolic Blood Pressure (xxx)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                         | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)                       | 15 Feb 2021 16:53:21 |
| User entered '78'         | (b) (4)<br>Traci Hull (b) (4)<br>(b) (4) | 31 Aug 2020 13:35:48 |

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:34

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered 'mmHg' | System           | 31 Aug 2020 13:35:48 |

**US3402139**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:26:34**

[Was the physical examination performed?](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                         | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)                       | 15 Feb 2021 16:53:21 |
| User entered 'Yes (Y)'    | (b) (4)<br>Traci Hull (b) (4)<br>(b) (4) | 31 Aug 2020 13:35:56 |

**US3402139**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:26:34**

**Date of examination (dd MMM yyyy)**

| Audit                      | User               | Time (GMT)           |
|----------------------------|--------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded.  | Frank Eder (b) (4) | 15 Feb 2021 16:53:21 |
| User entered '31 Aug 2020' | Traci Hull (b) (4) | 31 Aug 2020 13:35:56 |

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:34

[Was study treatment given?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:21 |
| User entered 'Yes (Y)'    | (b) (4)<br>Abigail Wine (b) (4) | 31 Aug 2020 12:56:03 |



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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:34

[If No, reason not given](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:21 |
| User entered empty.       | (b) (4)<br>Abigail Wine (b) (4) | 31 Aug 2020 12:56:03 |

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:34

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)   | 15 Feb 2021 16:53:21 |
| User entered empty.       | Abigail Wine (b) (4) | 31 Aug 2020 12:56:03 |

US3402139

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:34

[What was the study treatment?](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| Data hard locked.                   | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered 'MRNA-1273 OR PLACEBO' | System           | 31 Aug 2020 12:56:03 |

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:34

What was the treatment date? (dd MMM yyyy)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                | 27 Mar 2021 18:38:17 |
| User signature succeeded.  | Frank Eder (b) (4)              | 15 Feb 2021 16:53:21 |
| User entered '31 Aug 2020' | (b) (4)<br>Abigail Wine (b) (4) | 31 Aug 2020 12:56:03 |

US3402139

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:34

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Feb 2021 16:53:21 |
| User entered '08:40'      | (b) (4)<br>Abigail Wine (b) (4) | 31 Aug 2020 12:56:03 |

**US3402139**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:26:34**

[Treatment Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered '31 Aug 2020 08:40' | System           | 31 Aug 2020 12:56:03 |

US3402139

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:34

[Which arm was used to give treatment?](#)

| Audit                              | User                 | Time (GMT)           |
|------------------------------------|----------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)     | 27 Mar 2021 18:38:17 |
| User signature succeeded.          | Frank Eder (b) (4)   | 15 Feb 2021 16:53:21 |
| User entered 'Left Arm (LEFT ARM)' | Abigail Wine (b) (4) | 31 Aug 2020 12:56:03 |

US3402139

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:34

[What was the frequency of the study treatment dosing?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered 'ONCE' | System           | 31 Aug 2020 12:56:03 |



US3402139

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:34

What was the route of administration for the study treatment?

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered 'INTRAMUSCULAR' | System           | 31 Aug 2020 12:56:03 |

**US3402139**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:26:34**

[Was the sample collected?](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)              | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)            | 15 Feb 2021 16:53:21 |
| User entered 'Yes (Y)'    | (b) (4)<br>Traci Hull (b) (4) | 31 Aug 2020 13:36:10 |

**US3402139**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:26:34**

**Collection date** (*dd MMM yyyy*)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)              | 27 Mar 2021 18:38:17 |
| User signature succeeded.  | Frank Eder (b) (4)            | 15 Feb 2021 16:53:21 |
| User entered '31 Aug 2020' | (b) (4)<br>Traci Hull (b) (4) | 31 Aug 2020 13:36:10 |

**US3402139**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:26:34**

[Collection time \(00:00-23:59\)](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 16:53:21 |
| User entered '08:33'      | Traci Hull (b) (4) | 31 Aug 2020 13:36:10 |

**US3402139**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:26:34**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered '31 Aug 2020 08:33' | System           | 31 Aug 2020 13:36:10 |

**US3402139**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 09 Jun 2021 17:26:34**

**Collection date** (*dd MMM yyyy*)

| Audit                      | User               | Time (GMT)           |
|----------------------------|--------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded.  | Frank Eder (b) (4) | 15 Feb 2021 16:53:21 |
| User entered '31 Aug 2020' | Traci Hull (b) (4) | 31 Aug 2020 13:36:22 |

**US3402139**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:26:34**

[Lab Test](#)

| Audit  | User                          | Time (GMT)           |
|--|-------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)              | 27 Mar 2021 18:38:17 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Traci Hull (b) (4)<br>(b) (4) | 31 Aug 2020 13:36:22 |

**US3402139**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:26:34**

[Was the sample collected?](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                         | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)                       | 15 Feb 2021 16:53:21 |
| User entered 'Yes (Y)'    | (b) (4)<br>Traci Hull (b) (4)<br>(b) (4) | 31 Aug 2020 13:36:22 |



**US3402139**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:26:34**

**Collection time (00:00 - 23:59)**

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 16:53:21 |
| User entered '08:35'      | Traci Hull (b) (4) | 31 Aug 2020 13:36:22 |

**US3402139**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:26:34**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered '31 Aug 2020 08:35' | System           | 31 Aug 2020 13:36:22 |

**US3402139**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:26:34**

[Lab Test](#)

| Audit  | User                          | Time (GMT)           |
|--|-------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)              | 27 Mar 2021 18:38:17 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Traci Hull (b) (4)<br>(b) (4) | 31 Aug 2020 13:36:22 |

**US3402139**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:26:34**

[Was the sample collected?](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                         | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)                       | 15 Feb 2021 16:53:21 |
| User entered 'No (N)'     | (b) (4)<br>Traci Hull (b) (4)<br>(b) (4) | 31 Aug 2020 13:36:22 |

**US3402139**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:26:34**

[Collection time \(00:00 - 23:59\)](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 16:53:21 |
| User entered empty.       | Traci Hull (b) (4) | 31 Aug 2020 13:36:22 |

**US3402139**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:26:34**

[Collection date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered empty. | System           | 31 Aug 2020 13:36:22 |

US3402139

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:34

[Is the participant continuing to the next visit?](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                         | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)                       | 15 Feb 2021 16:53:21 |
| User entered 'Yes (Y)'    | (b) (4)<br>Traci Hull (b) (4)<br>(b) (4) | 31 Aug 2020 13:36:27 |

**US3402139**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:26:34**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered 'I'  | System           | 31 Aug 2020 13:36:27 |



US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.   | System           | 31 Aug 2020 12:56:03 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 31 Aug 2020 12:56:03 |

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T09:10:45', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'cf875289-ec06-4636-b8c0-44bfa9779f74' | System           | 31 Aug 2020 13:11:19 |
| User entered 'Yes (Y)'  | System           | 31 Aug 2020 13:11:19 |

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

Please record your **TEMPERATURE** in °F

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T09:11:04', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'cf875289-ec06-4636-b8c0-44bfa9779f74' User entered '98.2' | System           | 31 Aug 2020 13:11:19 |
|   | System           | 31 Aug 2020 13:11:19 |

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T09:11:08', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'cf875289-ec06-4636-b8c0-44bfa9779f74' | System           | 31 Aug 2020 13:11:19 |
| User entered 'No (N)'   | System           | 31 Aug 2020 13:11:19 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T09:11:15', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'cf875289-ec06-4636-b8c0-44bfa9779f74' | System           | 31 Aug 2020 13:11:19 |
| User entered '31 Aug 2020 09:11'  | System           | 31 Aug 2020 13:11:19 |

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '31 Aug 2020 09:00' | System           | 31 Aug 2020 12:56:03 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '31 Aug 2020 11:30' | System           | 31 Aug 2020 12:56:03 |

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.                                | System           | 31 Aug 2020 12:56:03 |
| User entered 'Day 1, after vaccination (at home)' | System           | 31 Aug 2020 12:56:03 |



US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T13:25:38', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '591a24d4-0b88-4d3e-a3b2-496042749d48' | System           | 31 Aug 2020 17:27:20 |
| User entered 'Yes (Y)'  | System           | 31 Aug 2020 17:27:20 |

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

Please record your **TEMPERATURE** in °F

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T13:25:43', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '591a24d4-0b88-4d3e-a3b2-496042749d48' User entered '97.9' | System           | 31 Aug 2020 17:27:20 |
|   | System           | 31 Aug 2020 17:27:20 |

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T13:25:46', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '591a24d4-0b88-4d3e-a3b2-496042749d48' | System           | 31 Aug 2020 17:27:20 |
| User entered 'No (N)'   | System           | 31 Aug 2020 17:27:20 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T13:25:48', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '591a24d4-0b88-4d3e-a3b2-496042749d48' | System           | 31 Aug 2020 17:27:20 |
| User entered '31 Aug 2020 13:25'  | System           | 31 Aug 2020 17:27:20 |

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '31 Aug 2020 12:25' | System           | 31 Aug 2020 12:56:03 |

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '01 Sep 2020 11:59' | System           | 31 Aug 2020 12:56:03 |

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.   | System           | 31 Aug 2020 12:56:03 |
| User entered 'Day 2' | System           | 31 Aug 2020 12:56:03 |

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:26:34

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-01T16:11:36', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '893b4f5b-0c37-407c-bf97-cda312fa30d2' | System           | 01 Sep 2020 20:11:58 |
| User entered 'Yes (Y)'  | System           | 01 Sep 2020 20:11:58 |



US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:26:34

Please record your **TEMPERATURE** in °F

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-01T16:11:43', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '893b4f5b-0c37-407c-bf97-cda312fa30d2' | System           | 01 Sep 2020 20:11:58 |
| User entered '99.2'   | System           | 01 Sep 2020 20:11:58 |

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:26:34

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-01T16:11:47', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '893b4f5b-0c37-407c-bf97-cda312fa30d2' | System           | 01 Sep 2020 20:11:58 |
| User entered 'Yes (Y)'  | System           | 01 Sep 2020 20:11:58 |

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:26:34

To **TREAT** pain or fever that has already occurred

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)     | 05 Mar 2021 03:55:53 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed added to con med ' (Site from System). | (b) (4), (b) (6)     | 09 Sep 2020 09:48:56 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'  | Tarin Gordon (b) (4) | 08 Sep 2020 15:08:45 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-01T16:11:54', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '893b4f5b-0c37-407c-bf97-cda312fa30d2'   | (b) (4)              |                      |
| User entered '1'  | System               | 01 Sep 2020 20:11:58 |
|   | System               | 01 Sep 2020 20:11:58 |
|   | System               | 01 Sep 2020 20:11:58 |

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:26:34

To **PREVENT** pain or fever from occurring

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-01T16:11:54', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '893b4f5b-0c37-407c-bf97-cda312fa30d2' | System           | 01 Sep 2020 20:11:58 |
| User entered '0'  | System           | 01 Sep 2020 20:11:58 |

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:26:34

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-01T16:11:57', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '893b4f5b-0c37-407c-bf97-cda312fa30d2' | System           | 01 Sep 2020 20:11:58 |
| User entered '01 Sep 2020 16:11'  | System           | 01 Sep 2020 20:11:58 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '01 Sep 2020 12:00' | System           | 31 Aug 2020 12:56:03 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '02 Sep 2020 11:59' | System           | 31 Aug 2020 12:56:03 |

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.   | System           | 31 Aug 2020 12:56:03 |
| User entered 'Day 3' | System           | 31 Aug 2020 12:56:03 |



US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:26:34

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-02T13:52:15', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '73dfe5da-7ba5-402f-817e-74d2660fddbf' | System           | 02 Sep 2020 17:52:26 |
| User entered 'Yes (Y)'  | System           | 02 Sep 2020 17:52:26 |

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:26:34

Please record your **TEMPERATURE** in °F

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-02T13:52:19', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '73dfe5da-7ba5-402f-817e-74d2660fddbf' | System           | 02 Sep 2020 17:52:26 |
| User entered '98.7'   | System           | 02 Sep 2020 17:52:26 |

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:26:34

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-02T13:52:22', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '73dfe5da-7ba5-402f-817e-74d2660fddbf' | System           | 02 Sep 2020 17:52:26 |
| User entered 'No (N)'   | System           | 02 Sep 2020 17:52:26 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-02T13:52:24', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '73dfe5da-7ba5-402f-817e-74d2660fddbf' | System           | 02 Sep 2020 17:52:26 |
| User entered '02 Sep 2020 13:52'  | System           | 02 Sep 2020 17:52:26 |

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:26:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '02 Sep 2020 12:00' | System           | 31 Aug 2020 12:56:03 |

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:26:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '03 Sep 2020 11:59' | System           | 31 Aug 2020 12:56:03 |

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.   | System           | 31 Aug 2020 12:56:03 |
| User entered 'Day 4' | System           | 31 Aug 2020 12:56:03 |

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:26:34

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-03T12:41:04', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b91ea3d7-081a-4230-ae70-7fd974171ac6' | System           | 03 Sep 2020 16:41:17 |
| User entered 'Yes (Y)'   | System           | 03 Sep 2020 16:41:17 |



US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:26:34

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-03T12:41:08', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b91ea3d7-081a-4230-ae70-7fd974171ac6' | System           | 03 Sep 2020 16:41:17 |
| User entered '98.4'  | System           | 03 Sep 2020 16:41:17 |

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:26:34

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-03T12:41:11', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b91ea3d7-081a-4230-ae70-7fd974171ac6' | System           | 03 Sep 2020 16:41:17 |
| User entered 'No (N)'  | System           | 03 Sep 2020 16:41:17 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-03T12:41:13', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b91ea3d7-081a-4230-ae70-7fd974171ac6' | System           | 03 Sep 2020 16:41:17 |
| User entered '03 Sep 2020 12:41'   | System           | 03 Sep 2020 16:41:17 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '03 Sep 2020 12:00' | System           | 31 Aug 2020 12:56:03 |

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:26:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '04 Sep 2020 11:59' | System           | 31 Aug 2020 12:56:03 |

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.   | System           | 31 Aug 2020 12:56:03 |
| User entered 'Day 5' | System           | 31 Aug 2020 12:56:03 |

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:26:34

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-04T12:02:46', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'f1f3669f-658a-45c5-a802-1009608e5b32' | System           | 04 Sep 2020 16:04:48 |
| User entered 'Yes (Y)'   | System           | 04 Sep 2020 16:04:48 |

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:26:34

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-04T12:02:50', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'f1f3669f-658a-45c5-a802-1009608e5b32' | System           | 04 Sep 2020 16:04:48 |
| User entered '97.4'  | System           | 04 Sep 2020 16:04:48 |



US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:26:34

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-04T12:02:52', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'f1f3669f-658a-45c5-a802-1009608e5b32' | System           | 04 Sep 2020 16:04:48 |
| User entered 'No (N)'  | System           | 04 Sep 2020 16:04:48 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-04T12:02:54', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'f1f3669f-658a-45c5-a802-1009608e5b32' | System           | 04 Sep 2020 16:04:48 |
| User entered '04 Sep 2020 12:02'   | System           | 04 Sep 2020 16:04:48 |

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:26:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '04 Sep 2020 12:00' | System           | 31 Aug 2020 12:56:03 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '05 Sep 2020 11:59' | System           | 31 Aug 2020 12:56:03 |

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.   | System           | 31 Aug 2020 12:56:03 |
| User entered 'Day 6' | System           | 31 Aug 2020 12:56:03 |

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:26:34

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-05T12:03:52', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '6d15294c-fec6-4ab8-8745-d70b00c62f71' | System           | 05 Sep 2020 16:05:08 |
| User entered 'Yes (Y)'   | System           | 05 Sep 2020 16:05:08 |

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:26:34

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-05T12:03:56', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '6d15294c-fec6-4ab8-8745-d70b00c62f71' | System           | 05 Sep 2020 16:05:08 |
| User entered '97.1'  | System           | 05 Sep 2020 16:05:08 |

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:26:34

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-05T12:04:00', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '6d15294c-fec6-4ab8-8745-d70b00c62f71' | System           | 05 Sep 2020 16:05:08 |
| User entered 'No (N)'  | System           | 05 Sep 2020 16:05:08 |



**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-05T12:04:04', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '6d15294c-fec6-4ab8-8745-d70b00c62f71' | System           | 05 Sep 2020 16:05:08 |
| User entered '05 Sep 2020 12:04'   | System           | 05 Sep 2020 16:05:08 |

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:26:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '05 Sep 2020 12:00' | System           | 31 Aug 2020 12:56:03 |

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:26:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '06 Sep 2020 11:59' | System           | 31 Aug 2020 12:56:03 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.   | System           | 31 Aug 2020 12:56:03 |
| User entered 'Day 7' | System           | 31 Aug 2020 12:56:03 |

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:26:34

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-06T20:41:25', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '157c0a52-8cff-450a-9c2d-7e07440c409f' | System           | 07 Sep 2020 00:41:49 |
| User entered 'Yes (Y)'   | System           | 07 Sep 2020 00:41:49 |

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:26:34

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-06T20:41:37', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '157c0a52-8cff-450a-9c2d-7e07440c409f' User entered '97.3' | System           | 07 Sep 2020 00:41:49 |

US3402139

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:26:34

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-06T20:41:40', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '157c0a52-8cff-450a-9c2d-7e07440c409f' | System           | 07 Sep 2020 00:41:49 |
| User entered 'No (N)'  | System           | 07 Sep 2020 00:41:49 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-06T20:41:42', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '157c0a52-8cff-450a-9c2d-7e07440c409f' | System           | 07 Sep 2020 00:41:49 |
| User entered '06 Sep 2020 20:41'   | System           | 07 Sep 2020 00:41:49 |



**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '06 Sep 2020 12:00' | System           | 31 Aug 2020 12:56:03 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '07 Sep 2020 11:59' | System           | 31 Aug 2020 12:56:03 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.   | System           | 31 Aug 2020 12:56:03 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 31 Aug 2020 12:56:03 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T09:11:39', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '33dbe681-b3e8-4515-8c8c-1ce97463743b' | System           | 31 Aug 2020 13:12:49 |
| User entered 'None (1)'   | System           | 31 Aug 2020 13:12:49 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

Is there any **REDNESS AT INJECTION SITE?**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T09:12:33', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '33dbe681-b3e8-4515-8c8c-1ce97463743b' | System           | 31 Aug 2020 13:12:49 |
| User entered 'No (N)'   | System           | 31 Aug 2020 13:12:49 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T09:12:36', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '33dbe681-b3e8-4515-8c8c-1ce97463743b' | System           | 31 Aug 2020 13:12:49 |
| User entered 'No (N)'   | System           | 31 Aug 2020 13:12:49 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T09:12:42', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '33dbe681-b3e8-4515-8c8c-1ce97463743b' | System           | 31 Aug 2020 13:12:49 |
| User entered 'None (1)'   | System           | 31 Aug 2020 13:12:49 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T09:12:45', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '33dbe681-b3e8-4515-8c8c-1ce97463743b' | System           | 31 Aug 2020 13:12:49 |
| User entered '31 Aug 2020 09:12'  | System           | 31 Aug 2020 13:12:49 |



**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '31 Aug 2020 09:00' | System           | 31 Aug 2020 12:56:03 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '31 Aug 2020 11:30' | System           | 31 Aug 2020 12:56:03 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.                                | System           | 31 Aug 2020 12:56:03 |
| User entered 'Day 1, after vaccination (at home)' | System           | 31 Aug 2020 12:56:03 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T13:25:53', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'a7e4c1a5-6741-4539-8659-b900e6a5ad6a' | System           | 31 Aug 2020 17:27:23 |
| User entered 'None (1)'   | System           | 31 Aug 2020 17:27:23 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

Is there any **REDNESS AT INJECTION SITE?**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T13:25:55', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'a7e4c1a5-6741-4539-8659-b900e6a5ad6a' | System           | 31 Aug 2020 17:27:23 |
| User entered 'No (N)'   | System           | 31 Aug 2020 17:27:23 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T13:25:58', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'a7e4c1a5-6741-4539-8659-b900e6a5ad6a' | System           | 31 Aug 2020 17:27:23 |
| User entered 'No (N)'   | System           | 31 Aug 2020 17:27:23 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T13:26:00', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'a7e4c1a5-6741-4539-8659-b900e6a5ad6a' | System           | 31 Aug 2020 17:27:23 |
| User entered 'None (1)'   | System           | 31 Aug 2020 17:27:23 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T13:26:04', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'a7e4c1a5-6741-4539-8659-b900e6a5ad6a' | System           | 31 Aug 2020 17:27:23 |
| User entered '31 Aug 2020 13:26'  | System           | 31 Aug 2020 17:27:23 |



**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '31 Aug 2020 12:25' | System           | 31 Aug 2020 12:56:03 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '01 Sep 2020 11:59' | System           | 31 Aug 2020 12:56:03 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.   | System           | 31 Aug 2020 12:56:03 |
| User entered 'Day 2' | System           | 31 Aug 2020 12:56:03 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-01T16:12:15', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '6a1c103e-ade0-459c-8246-162a1d85f5b7' | System           | 01 Sep 2020 20:13:12 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'  | System           | 01 Sep 2020 20:13:12 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:26:34

Is there any REDNESS AT INJECTION SITE?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-01T16:12:41', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '6a1c103e-ade0-459c-8246-162a1d85f5b7' | System           | 01 Sep 2020 20:13:12 |
| User entered 'No (N)'   | System           | 01 Sep 2020 20:13:12 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:26:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-01T16:12:53', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '6a1c103e-ade0-459c-8246-162a1d85f5b7' | System           | 01 Sep 2020 20:13:12 |
| User entered 'No (N)'   | System           | 01 Sep 2020 20:13:12 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-01T16:13:07', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '6a1c103e-ade0-459c-8246-162a1d85f5b7' | System           | 01 Sep 2020 20:13:12 |
| User entered 'None (1)'   | System           | 01 Sep 2020 20:13:12 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:26:34

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-01T16:13:12', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '6a1c103e-ade0-459c-8246-162a1d85f5b7' | System           | 01 Sep 2020 20:13:12 |
| User entered '01 Sep 2020 16:13'  | System           | 01 Sep 2020 20:13:12 |



**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '01 Sep 2020 12:00' | System           | 31 Aug 2020 12:56:03 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '02 Sep 2020 11:59' | System           | 31 Aug 2020 12:56:03 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.   | System           | 31 Aug 2020 12:56:03 |
| User entered 'Day 3' | System           | 31 Aug 2020 12:56:03 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-02T13:50:27', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '5f76fd72-8c05-4af6-a662-d812854c319e' | System           | 02 Sep 2020 17:50:41 |
| User entered 'Does not interfere with activity (2)'   | System           | 02 Sep 2020 17:50:41 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:26:34

Is there any **REDNESS AT INJECTION SITE?**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-02T13:50:29', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '5f76fd72-8c05-4af6-a662-d812854c319e' | System           | 02 Sep 2020 17:50:41 |
| User entered 'No (N)'   | System           | 02 Sep 2020 17:50:41 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:26:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-02T13:50:32', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '5f76fd72-8c05-4af6-a662-d812854c319e' | System           | 02 Sep 2020 17:50:41 |
| User entered 'No (N)'   | System           | 02 Sep 2020 17:50:41 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-02T13:50:37', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '5f76fd72-8c05-4af6-a662-d812854c319e' | System           | 02 Sep 2020 17:50:41 |
| User entered 'None (1)'   | System           | 02 Sep 2020 17:50:41 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:26:34

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-02T13:50:39', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '5f76fd72-8c05-4af6-a662-d812854c319e' | System           | 02 Sep 2020 17:50:41 |
| User entered '02 Sep 2020 13:50'  | System           | 02 Sep 2020 17:50:41 |



**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '02 Sep 2020 12:00' | System           | 31 Aug 2020 12:56:03 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '03 Sep 2020 11:59' | System           | 31 Aug 2020 12:56:03 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.   | System           | 31 Aug 2020 12:56:03 |
| User entered 'Day 4' | System           | 31 Aug 2020 12:56:03 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-03T12:39:45', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '24df77ef-d015-4333-ab85-3bf1e40dccf8' | System           | 03 Sep 2020 16:39:59 |
| User entered 'Does not interfere with activity (2)'  | System           | 03 Sep 2020 16:39:59 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:26:34

Is there any **REDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-03T12:39:47', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '24df77ef-d015-4333-ab85-3bf1e40dccf8' | System           | 03 Sep 2020 16:39:59 |
| User entered 'No (N)'  | System           | 03 Sep 2020 16:39:59 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:26:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-03T12:39:50', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '24df77ef-d015-4333-ab85-3bf1e40dccf8' | System           | 03 Sep 2020 16:39:59 |
| User entered 'No (N)'  | System           | 03 Sep 2020 16:39:59 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-03T12:39:52', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '24df77ef-d015-4333-ab85-3bf1e40dccf8' | System           | 03 Sep 2020 16:39:59 |
| User entered 'None (1)'  | System           | 03 Sep 2020 16:39:59 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:26:34

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-03T12:39:54', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '24df77ef-d015-4333-ab85-3bf1e40dccf8' | System           | 03 Sep 2020 16:39:59 |
| User entered '03 Sep 2020 12:39'   | System           | 03 Sep 2020 16:39:59 |



**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '03 Sep 2020 12:00' | System           | 31 Aug 2020 12:56:03 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '04 Sep 2020 11:59' | System           | 31 Aug 2020 12:56:03 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.   | System           | 31 Aug 2020 12:56:03 |
| User entered 'Day 5' | System           | 31 Aug 2020 12:56:03 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-04T12:02:28', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '96def872-91c7-4231-b98a-21bc9ca9a037' | System           | 04 Sep 2020 16:04:26 |
| User entered 'Does not interfere with activity (2)'  | System           | 04 Sep 2020 16:04:26 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:26:34

Is there any **REDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-04T12:02:32', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '96def872-91c7-4231-b98a-21bc9ca9a037' | System           | 04 Sep 2020 16:04:26 |
| User entered 'No (N)'  | System           | 04 Sep 2020 16:04:26 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:26:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-04T12:02:34', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '96def872-91c7-4231-b98a-21bc9ca9a037' | System           | 04 Sep 2020 16:04:26 |
| User entered 'No (N)'  | System           | 04 Sep 2020 16:04:26 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-04T12:02:38', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '96def872-91c7-4231-b98a-21bc9ca9a037' | System           | 04 Sep 2020 16:04:26 |
| User entered 'None (1)'  | System           | 04 Sep 2020 16:04:26 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:26:34

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-04T12:02:40', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '96def872-91c7-4231-b98a-21bc9ca9a037' | System           | 04 Sep 2020 16:04:26 |
| User entered '04 Sep 2020 12:02'   | System           | 04 Sep 2020 16:04:26 |



**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '04 Sep 2020 12:00' | System           | 31 Aug 2020 12:56:03 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '05 Sep 2020 11:59' | System           | 31 Aug 2020 12:56:03 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.   | System           | 31 Aug 2020 12:56:03 |
| User entered 'Day 6' | System           | 31 Aug 2020 12:56:03 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-05T12:04:11', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '60dbba51-bb9f-4333-8e19-acf62a009027' | System           | 05 Sep 2020 16:05:19 |
| User entered 'None (1)'  | System           | 05 Sep 2020 16:05:19 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:26:34

Is there any **REDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-05T12:04:14', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '60dbba51-bb9f-4333-8e19-acf62a009027' | System           | 05 Sep 2020 16:05:19 |
| User entered 'No (N)'  | System           | 05 Sep 2020 16:05:19 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:26:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-05T12:04:17', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '60dbba51-bb9f-4333-8e19-acf62a009027' | System           | 05 Sep 2020 16:05:19 |
| User entered 'No (N)'  | System           | 05 Sep 2020 16:05:19 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-05T12:04:21', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '60dbba51-bb9f-4333-8e19-acf62a009027' | System           | 05 Sep 2020 16:05:19 |
| User entered 'None (1)'  | System           | 05 Sep 2020 16:05:19 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:26:34

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-05T12:04:23', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '60dbba51-bb9f-4333-8e19-acf62a009027' | System           | 05 Sep 2020 16:05:19 |
| User entered '05 Sep 2020 12:04'   | System           | 05 Sep 2020 16:05:19 |



**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '05 Sep 2020 12:00' | System           | 31 Aug 2020 12:56:03 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '06 Sep 2020 11:59' | System           | 31 Aug 2020 12:56:03 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.   | System           | 31 Aug 2020 12:56:03 |
| User entered 'Day 7' | System           | 31 Aug 2020 12:56:03 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-06T20:41:47', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '8ce7960f-3867-4315-a24d-0baecd8b06ab' | System           | 07 Sep 2020 00:41:59 |
| User entered 'None (1)'  | System           | 07 Sep 2020 00:41:59 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:26:34

Is there any **REDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-06T20:41:49', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '8ce7960f-3867-4315-a24d-0baecd8b06ab' | System           | 07 Sep 2020 00:41:59 |
| User entered 'No (N)'  | System           | 07 Sep 2020 00:41:59 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:26:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-06T20:41:52', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '8ce7960f-3867-4315-a24d-0baecd8b06ab' | System           | 07 Sep 2020 00:41:59 |
| User entered 'No (N)'  | System           | 07 Sep 2020 00:41:59 |

US3402139

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-06T20:41:54', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '8ce7960f-3867-4315-a24d-0baecd8b06ab' | System           | 07 Sep 2020 00:41:59 |
| User entered 'None (1)'  | System           | 07 Sep 2020 00:41:59 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-06T20:41:57', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '8ce7960f-3867-4315-a24d-0baecd8b06ab' | System           | 07 Sep 2020 00:41:59 |
| User entered '06 Sep 2020 20:41'   | System           | 07 Sep 2020 00:41:59 |



**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '06 Sep 2020 12:00' | System           | 31 Aug 2020 12:56:03 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '07 Sep 2020 11:59' | System           | 31 Aug 2020 12:56:03 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.   | System           | 31 Aug 2020 12:56:03 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 31 Aug 2020 12:56:03 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

**HEADACHE**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T09:12:49', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '90e96343-aa5c-4d06-97c8-65cb18285e77' | System           | 31 Aug 2020 13:13:17 |
| User entered 'None (0)'   | System           | 31 Aug 2020 13:13:17 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

**FATIGUE**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T09:12:52', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '90e96343-aa5c-4d06-97c8-65cb18285e77' | System           | 31 Aug 2020 13:13:17 |
| User entered 'None (0)'   | System           | 31 Aug 2020 13:13:17 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

**MUSCLE ACHES ALL OVER BODY**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T09:12:54', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '90e96343-aa5c-4d06-97c8-65cb18285e77' | System           | 31 Aug 2020 13:13:17 |
| User entered 'None (0)'   | System           | 31 Aug 2020 13:13:17 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

**JOINT ACHES IN SEVERAL JOINTS**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T09:12:57', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '90e96343-aa5c-4d06-97c8-65cb18285e77' | System           | 31 Aug 2020 13:13:17 |
| User entered 'None (0)'   | System           | 31 Aug 2020 13:13:17 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

**NAUSEA/VOMITING**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T09:13:00', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '90e96343-aa5c-4d06-97c8-65cb18285e77' | System           | 31 Aug 2020 13:13:17 |
| User entered 'None (0)'   | System           | 31 Aug 2020 13:13:17 |



US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

**CHILLS**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T09:13:03', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '90e96343-aa5c-4d06-97c8-65cb18285e77' | System           | 31 Aug 2020 13:13:17 |
| User entered 'None (0)'   | System           | 31 Aug 2020 13:13:17 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T09:13:08', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '90e96343-aa5c-4d06-97c8-65cb18285e77' | System           | 31 Aug 2020 13:13:17 |
| User entered 'No (N)'   | System           | 31 Aug 2020 13:13:17 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T09:13:15', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '90e96343-aa5c-4d06-97c8-65cb18285e77' | System           | 31 Aug 2020 13:13:17 |
| User entered '31 Aug 2020 09:13'  | System           | 31 Aug 2020 13:13:17 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '31 Aug 2020 09:00' | System           | 31 Aug 2020 12:56:03 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '31 Aug 2020 11:30' | System           | 31 Aug 2020 12:56:03 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.                                | System           | 31 Aug 2020 12:56:03 |
| User entered 'Day 1, after vaccination (at home)' | System           | 31 Aug 2020 12:56:03 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

**HEADACHE**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T13:26:08', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'bef6547c-cad2-433b-ba02-199329348a36' | System           | 31 Aug 2020 17:27:40 |
| User entered 'None (0)'   | System           | 31 Aug 2020 17:27:40 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

**FATIGUE**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T13:26:10', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'bef6547c-cad2-433b-ba02-199329348a36' | System           | 31 Aug 2020 17:27:40 |
| User entered 'None (0)'   | System           | 31 Aug 2020 17:27:40 |



US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

**MUSCLE ACHES ALL OVER BODY**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T13:26:11', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'bef6547c-cad2-433b-ba02-199329348a36' | System           | 31 Aug 2020 17:27:40 |
| User entered 'None (0)'   | System           | 31 Aug 2020 17:27:40 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

**JOINT ACHES IN SEVERAL JOINTS**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T13:26:13', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'bef6547c-cad2-433b-ba02-199329348a36' | System           | 31 Aug 2020 17:27:40 |
| User entered 'None (0)'   | System           | 31 Aug 2020 17:27:40 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

**NAUSEA/VOMITING**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T13:26:15', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'bef6547c-cad2-433b-ba02-199329348a36' | System           | 31 Aug 2020 17:27:40 |
| User entered 'None (0)'   | System           | 31 Aug 2020 17:27:40 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

**CHILLS**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T13:26:17', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'bef6547c-cad2-433b-ba02-199329348a36' | System           | 31 Aug 2020 17:27:40 |
| User entered 'None (0)'   | System           | 31 Aug 2020 17:27:40 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T13:26:21', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'bef6547c-cad2-433b-ba02-199329348a36' | System           | 31 Aug 2020 17:27:40 |
| User entered 'No (N)'   | System           | 31 Aug 2020 17:27:40 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-08-31T13:26:23', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'bef6547c-cad2-433b-ba02-199329348a36' | System           | 31 Aug 2020 17:27:40 |
| User entered '31 Aug 2020 13:26'  | System           | 31 Aug 2020 17:27:40 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '31 Aug 2020 12:25' | System           | 31 Aug 2020 12:56:03 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '01 Sep 2020 11:59' | System           | 31 Aug 2020 12:56:03 |



**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.   | System           | 31 Aug 2020 12:56:03 |
| User entered 'Day 2' | System           | 31 Aug 2020 12:56:03 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:26:34

**HEADACHE**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-01T16:13:19', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '11cc5cd0-fa87-4705-bfe1-78d9733f6c1b' | System           | 01 Sep 2020 20:13:44 |
| User entered 'None (0)'   | System           | 01 Sep 2020 20:13:44 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:26:34

**FATIGUE**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-01T16:13:23', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '11cc5cd0-fa87-4705-bfe1-78d9733f6c1b' | System           | 01 Sep 2020 20:13:44 |
| User entered 'No interference with activity (1)'  | System           | 01 Sep 2020 20:13:44 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:26:34

**MUSCLE ACHES ALL OVER BODY**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-01T16:13:30', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '11cc5cd0-fa87-4705-bfe1-78d9733f6c1b' | System           | 01 Sep 2020 20:13:44 |
| User entered 'No interference with activity (1)'  | System           | 01 Sep 2020 20:13:44 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:26:34

**JOINT ACHES IN SEVERAL JOINTS**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-01T16:13:33', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '11cc5cd0-fa87-4705-bfe1-78d9733f6c1b' | System           | 01 Sep 2020 20:13:44 |
| User entered 'None (0)'   | System           | 01 Sep 2020 20:13:44 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:26:34

**NAUSEA/VOMITING**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-01T16:13:35', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '11cc5cd0-fa87-4705-bfe1-78d9733f6c1b' | System           | 01 Sep 2020 20:13:44 |
| User entered 'None (0)'   | System           | 01 Sep 2020 20:13:44 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:26:34

**CHILLS**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-01T16:13:38', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '11cc5cd0-fa87-4705-bfe1-78d9733f6c1b' | System           | 01 Sep 2020 20:13:44 |
| User entered 'None (0)'   | System           | 01 Sep 2020 20:13:44 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-01T16:13:41', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '11cc5cd0-fa87-4705-bfe1-78d9733f6c1b' | System           | 01 Sep 2020 20:13:44 |
| User entered 'No (N)'   | System           | 01 Sep 2020 20:13:44 |



**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-01T16:13:44', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '11cc5cd0-fa87-4705-bfe1-78d9733f6c1b' | System           | 01 Sep 2020 20:13:44 |
| User entered '01 Sep 2020 16:13'  | System           | 01 Sep 2020 20:13:44 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '01 Sep 2020 12:00' | System           | 31 Aug 2020 12:56:03 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '02 Sep 2020 11:59' | System           | 31 Aug 2020 12:56:03 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.   | System           | 31 Aug 2020 12:56:03 |
| User entered 'Day 3' | System           | 31 Aug 2020 12:56:03 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:26:34

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-02T13:49:56', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '397bce19-fcf3-4e91-b167-bc6ddddd455b0' | System           | 02 Sep 2020 17:50:21 |
| User entered 'None (0)'  | System           | 02 Sep 2020 17:50:21 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:26:34

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-02T13:50:01', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '397bce19-fcf3-4e91-b167-bc6ddddd455b0' | System           | 02 Sep 2020 17:50:21 |
| User entered 'None (0)'  | System           | 02 Sep 2020 17:50:21 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:26:34

**MUSCLE ACHES ALL OVER BODY**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-02T13:50:04', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '397bce19-fcf3-4e91-b167-bc6dddd455b0' | System           | 02 Sep 2020 17:50:21 |
| User entered 'None (0)'   | System           | 02 Sep 2020 17:50:21 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:26:34

**JOINT ACHES IN SEVERAL JOINTS**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-02T13:50:08', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '397bce19-fcf3-4e91-b167-bc6dddd455b0' | System           | 02 Sep 2020 17:50:21 |
| User entered 'None (0)'   | System           | 02 Sep 2020 17:50:21 |



US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:26:34

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-02T13:50:10', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '397bce19-fcf3-4e91-b167-bc6ddddd455b0' | System           | 02 Sep 2020 17:50:21 |
| User entered 'None (0)'  | System           | 02 Sep 2020 17:50:21 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:26:34

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-02T13:50:12', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '397bce19-fcf3-4e91-b167-bc6ddddd455b0' | System           | 02 Sep 2020 17:50:21 |
| User entered 'None (0)'  | System           | 02 Sep 2020 17:50:21 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-02T13:50:15', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '397bce19-fcf3-4e91-b167-bc6ddddd455b0' | System           | 02 Sep 2020 17:50:21 |
| User entered 'No (N)'  | System           | 02 Sep 2020 17:50:21 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (180d86ffcec3798)', Time: '2020-09-02T13:50:17', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '397bce19-fcf3-4e91-b167-bc6ddddd455b0' | System           | 02 Sep 2020 17:50:21 |
| User entered '02 Sep 2020 13:50'   | System           | 02 Sep 2020 17:50:21 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '02 Sep 2020 12:00' | System           | 31 Aug 2020 12:56:03 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '03 Sep 2020 11:59' | System           | 31 Aug 2020 12:56:03 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.   | System           | 31 Aug 2020 12:56:03 |
| User entered 'Day 4' | System           | 31 Aug 2020 12:56:03 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:26:34

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-03T12:40:09', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'bd6a9c9d-5eef-4b44-b6e5-5758f9fb0482' | System           | 03 Sep 2020 16:40:27 |
| User entered 'None (0)'  | System           | 03 Sep 2020 16:40:27 |



US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:26:34

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-03T12:40:11', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'bd6a9c9d-5eef-4b44-b6e5-5758f9fb0482' | System           | 03 Sep 2020 16:40:27 |
| User entered 'None (0)'  | System           | 03 Sep 2020 16:40:27 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:26:34

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-03T12:40:13', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'bd6a9c9d-5eef-4b44-b6e5-5758f9fb0482' | System           | 03 Sep 2020 16:40:27 |
| User entered 'None (0)'  | System           | 03 Sep 2020 16:40:27 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:26:34

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-03T12:40:14', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'bd6a9c9d-5eef-4b44-b6e5-5758f9fb0482' | System           | 03 Sep 2020 16:40:27 |
| User entered 'None (0)'  | System           | 03 Sep 2020 16:40:27 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:26:34

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-03T12:40:16', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'bd6a9c9d-5eef-4b44-b6e5-5758f9fb0482' | System           | 03 Sep 2020 16:40:27 |
| User entered 'None (0)'  | System           | 03 Sep 2020 16:40:27 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:26:34

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-03T12:40:18', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'bd6a9c9d-5eef-4b44-b6e5-5758f9fb0482' | System           | 03 Sep 2020 16:40:27 |
| User entered 'None (0)'  | System           | 03 Sep 2020 16:40:27 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-03T12:40:20', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'bd6a9c9d-5eef-4b44-b6e5-5758f9fb0482' | System           | 03 Sep 2020 16:40:27 |
| User entered 'No (N)'  | System           | 03 Sep 2020 16:40:27 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-03T12:40:23', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'bd6a9c9d-5eef-4b44-b6e5-5758f9fb0482' | System           | 03 Sep 2020 16:40:27 |
| User entered '03 Sep 2020 12:40'   | System           | 03 Sep 2020 16:40:27 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '03 Sep 2020 12:00' | System           | 31 Aug 2020 12:56:03 |



**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '04 Sep 2020 11:59' | System           | 31 Aug 2020 12:56:03 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:26:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.   | System           | 31 Aug 2020 12:56:03 |
| User entered 'Day 5' | System           | 31 Aug 2020 12:56:03 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:26:34

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-04T12:01:55', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'eefc1b6f-d3f8-43cc-919b-900456325886' | System           | 04 Sep 2020 16:03:52 |
| User entered 'None (0)'  | System           | 04 Sep 2020 16:03:52 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:26:34

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-04T12:01:57', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'eefc1b6f-d3f8-43cc-919b-900456325886' | System           | 04 Sep 2020 16:03:52 |
| User entered 'None (0)'  | System           | 04 Sep 2020 16:03:52 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:26:34

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-04T12:01:59', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'eefc1b6f-d3f8-43cc-919b-900456325886' | System           | 04 Sep 2020 16:03:52 |
| User entered 'None (0)'  | System           | 04 Sep 2020 16:03:52 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:26:34

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-04T12:02:01', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'eefc1b6f-d3f8-43cc-919b-900456325886' | System           | 04 Sep 2020 16:03:52 |
| User entered 'None (0)'  | System           | 04 Sep 2020 16:03:52 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:26:34

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-04T12:02:03', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'eefc1b6f-d3f8-43cc-919b-900456325886' | System           | 04 Sep 2020 16:03:52 |
| User entered 'None (0)'  | System           | 04 Sep 2020 16:03:52 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:26:34

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-04T12:02:05', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'eefc1b6f-d3f8-43cc-919b-900456325886' | System           | 04 Sep 2020 16:03:52 |
| User entered 'None (0)'  | System           | 04 Sep 2020 16:03:52 |



US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-04T12:02:09', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'eefc1b6f-d3f8-43cc-919b-900456325886' | System           | 04 Sep 2020 16:03:52 |
| User entered 'No (N)'  | System           | 04 Sep 2020 16:03:52 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-04T12:02:11', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'eefc1b6f-d3f8-43cc-919b-900456325886' | System           | 04 Sep 2020 16:03:52 |
| User entered '04 Sep 2020 12:02'   | System           | 04 Sep 2020 16:03:52 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '04 Sep 2020 12:00' | System           | 31 Aug 2020 12:56:03 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '05 Sep 2020 11:59' | System           | 31 Aug 2020 12:56:03 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.   | System           | 31 Aug 2020 12:56:03 |
| User entered 'Day 6' | System           | 31 Aug 2020 12:56:03 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:26:34

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-05T12:04:27', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '161682c6-9f53-4bd3-b980-5e5c983f8be9' | System           | 05 Sep 2020 16:05:53 |
| User entered 'None (0)'  | System           | 05 Sep 2020 16:05:53 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:26:34

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-05T12:04:28', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '161682c6-9f53-4bd3-b980-5e5c983f8be9' | System           | 05 Sep 2020 16:05:53 |
| User entered 'None (0)'  | System           | 05 Sep 2020 16:05:53 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:26:34

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-05T12:04:30', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '161682c6-9f53-4bd3-b980-5e5c983f8be9' | System           | 05 Sep 2020 16:05:53 |
| User entered 'None (0)'  | System           | 05 Sep 2020 16:05:53 |



US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:26:34

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-05T12:04:34', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '161682c6-9f53-4bd3-b980-5e5c983f8be9' | System           | 05 Sep 2020 16:05:53 |
| User entered 'None (0)'  | System           | 05 Sep 2020 16:05:53 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:26:34

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-05T12:04:38', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '161682c6-9f53-4bd3-b980-5e5c983f8be9' | System           | 05 Sep 2020 16:05:53 |
| User entered 'None (0)'  | System           | 05 Sep 2020 16:05:53 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:26:34

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-05T12:04:40', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '161682c6-9f53-4bd3-b980-5e5c983f8be9' | System           | 05 Sep 2020 16:05:53 |
| User entered 'None (0)'  | System           | 05 Sep 2020 16:05:53 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-05T12:04:43', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '161682c6-9f53-4bd3-b980-5e5c983f8be9' | System           | 05 Sep 2020 16:05:53 |
| User entered 'No (N)'  | System           | 05 Sep 2020 16:05:53 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-05T12:04:47', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '161682c6-9f53-4bd3-b980-5e5c983f8be9' | System           | 05 Sep 2020 16:05:53 |
| User entered '05 Sep 2020 12:04'   | System           | 05 Sep 2020 16:05:53 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '05 Sep 2020 12:00' | System           | 31 Aug 2020 12:56:03 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '06 Sep 2020 11:59' | System           | 31 Aug 2020 12:56:03 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.   | System           | 31 Aug 2020 12:56:03 |
| User entered 'Day 7' | System           | 31 Aug 2020 12:56:03 |



US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:26:34

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-06T20:42:01', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'ee8cd810-f937-496f-a736-9d53351ce2f0' | System           | 07 Sep 2020 00:42:26 |
| User entered 'None (0)'  | System           | 07 Sep 2020 00:42:26 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:26:34

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-06T20:42:03', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'ee8cd810-f937-496f-a736-9d53351ce2f0' | System           | 07 Sep 2020 00:42:26 |
| User entered 'None (0)'  | System           | 07 Sep 2020 00:42:26 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:26:34

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-06T20:42:05', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'ee8cd810-f937-496f-a736-9d53351ce2f0' | System           | 07 Sep 2020 00:42:26 |
| User entered 'None (0)'  | System           | 07 Sep 2020 00:42:26 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:26:34

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-06T20:42:09', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'ee8cd810-f937-496f-a736-9d53351ce2f0' | System           | 07 Sep 2020 00:42:26 |
| User entered 'None (0)'  | System           | 07 Sep 2020 00:42:26 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:26:34

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-06T20:42:12', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'ee8cd810-f937-496f-a736-9d53351ce2f0' | System           | 07 Sep 2020 00:42:26 |
| User entered 'None (0)'  | System           | 07 Sep 2020 00:42:26 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:26:34

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-06T20:42:15', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'ee8cd810-f937-496f-a736-9d53351ce2f0' | System           | 07 Sep 2020 00:42:26 |
| User entered 'None (0)'  | System           | 07 Sep 2020 00:42:26 |

US3402139

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:26:34

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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-06T20:42:18', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'ee8cd810-f937-496f-a736-9d53351ce2f0' | System           | 07 Sep 2020 00:42:26 |
| User entered 'No (N)'  | System           | 07 Sep 2020 00:42:26 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-09-06T20:42:20', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'ee8cd810-f937-496f-a736-9d53351ce2f0' | System           | 07 Sep 2020 00:42:26 |
| User entered '06 Sep 2020 20:42'   | System           | 07 Sep 2020 00:42:26 |



**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '06 Sep 2020 12:00' | System           | 31 Aug 2020 12:56:03 |

**US3402139**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:26:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| User entered '07 Sep 2020 11:59' | System           | 31 Aug 2020 12:56:03 |

**US3402139**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

[Was Contact Attempted?](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                         | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)                       | 15 Feb 2021 16:53:16 |
| User entered 'Yes (Y)'    | (b) (4)<br>Traci Hull (b) (4)<br>(b) (4) | 14 Sep 2020 13:59:01 |

**US3402139**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit   | User               | Time (GMT)           |
|---|--------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded.                                     | Frank Eder (b) (4) | 15 Feb 2021 16:53:16 |
| User entered '08 Sep 2020' reason for change: New Information | Traci Hull (b) (4) | 11 Nov 2020 12:32:10 |
| User entered '8 Sep 2020'                                     | Traci Hull (b) (4) | 14 Sep 2020 13:59:01 |

**US3402139**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

[Please select one status for the follow-up contact](#)

| Audit                                      | User               | Time (GMT)           |
|--|--------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded.                  | Frank Eder (b) (4) | 15 Feb 2021 16:53:16 |
| User entered 'Contact Made (CONTACT MADE)' | Traci Hull (b) (4) | 14 Sep 2020 13:59:01 |

**US3402139**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 16:53:16 |
| User entered empty.       | Traci Hull (b) (4) | 14 Sep 2020 13:59:01 |

**US3402139**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:26:34**

[Is the participant continuing to the next visit?](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 16:53:16 |
| User entered 'Yes (Y)'    | Traci Hull (b) (4) | 14 Sep 2020 13:58:48 |

**US3402139**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:26:34**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered 'I'  | System           | 14 Sep 2020 13:58:48 |



**US3402139**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

[Was Contact Attempted?](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 16:53:16 |
| User entered 'Yes (Y)'    | (b) (4)            | 15 Sep 2020 11:30:22 |
|                           | Traci Hull (b) (4) |                      |
|                           | (b) (4)            |                      |

**US3402139**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                      | User               | Time (GMT)           |
|----------------------------|--------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded.  | Frank Eder (b) (4) | 15 Feb 2021 16:53:16 |
| User entered '14 Sep 2020' | Traci Hull (b) (4) | 15 Sep 2020 11:30:22 |

**US3402139**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

[Please select one status for the follow-up contact](#)

| Audit                                      | User               | Time (GMT)           |
|--|--------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded.                  | Frank Eder (b) (4) | 15 Feb 2021 16:53:16 |
| User entered 'Contact Made (CONTACT MADE)' | Traci Hull (b) (4) | 15 Sep 2020 11:30:22 |

**US3402139**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 16:53:16 |
| User entered empty.       | Traci Hull (b) (4) | 15 Sep 2020 11:30:22 |

**US3402139**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:26:34**

[Is the participant continuing to the next visit?](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 16:53:16 |
| User entered 'Yes (Y)'    | Traci Hull (b) (4) | 15 Sep 2020 11:30:26 |

**US3402139**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:26:34**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered 'I'  | System           | 15 Sep 2020 11:30:26 |

**US3402139**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

[Was Contact Attempted?](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)              | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)            | 15 Feb 2021 16:53:16 |
| User entered 'Yes (Y)'    | (b) (4)<br>Traci Hull (b) (4) | 22 Sep 2020 11:50:12 |

**US3402139**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                      | User               | Time (GMT)           |
|----------------------------|--------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded.  | Frank Eder (b) (4) | 15 Feb 2021 16:53:16 |
| User entered '21 Sep 2020' | Traci Hull (b) (4) | 22 Sep 2020 11:50:12 |



**US3402139**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

[Please select one status for the follow-up contact](#)

| Audit                                      | User               | Time (GMT)           |
|--|--------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded.                  | Frank Eder (b) (4) | 15 Feb 2021 16:53:16 |
| User entered 'Contact Made (CONTACT MADE)' | Traci Hull (b) (4) | 22 Sep 2020 11:50:12 |

**US3402139**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 16:53:16 |
| User entered empty.       | Traci Hull (b) (4) | 22 Sep 2020 11:50:12 |

**US3402139**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:26:34**

[Is the participant continuing to the next visit?](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 16:53:16 |
| User entered 'Yes (Y)'    | Traci Hull (b) (4) | 22 Sep 2020 11:50:16 |

**US3402139**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:26:34**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered 'I'  | System           | 22 Sep 2020 11:50:16 |

**US3402139**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:26:34**

[Was this visit performed?](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)              | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)            | 15 Feb 2021 16:53:21 |
| User entered 'Yes (Y)'    | (b) (4)<br>Traci Hull (b) (4) | 25 Sep 2020 17:23:07 |

**US3402139**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:26:34**

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User               | Time (GMT)           |
|----------------------------|--------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded.  | Frank Eder (b) (4) | 15 Feb 2021 16:53:21 |
| User entered '25 Sep 2020' | (b) (4)            |                      |
|                            | Traci Hull (b) (4) | 25 Sep 2020 17:23:07 |
|                            | (b) (4)            |                      |

**US3402139**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:26:34**

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User               | Time (GMT)           |
|--------------------------------|--------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded.      | Frank Eder (b) (4) | 15 Feb 2021 16:53:21 |
| User entered 'Clinic (Clinic)' | Traci Hull (b) (4) | 25 Sep 2020 17:23:07 |

**US3402139**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:26:34**

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered 'VISIT3' | System           | 25 Sep 2020 17:23:07 |



US3402139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:34

[Were vital signs assessed?](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 16:53:21 |
| User entered 'Yes (Y)'    | Traci Hull (b) (4) | 25 Sep 2020 17:24:03 |

**US3402139**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:26:34**

**Date of assessment** (*dd MMM yyyy*)

| Audit                      | User                                     | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                         | 27 Mar 2021 18:38:17 |
| User signature succeeded.  | Frank Eder (b) (4)                       | 15 Feb 2021 16:53:21 |
| User entered '25 Sep 2020' | (b) (4)<br>Traci Hull (b) (4)<br>(b) (4) | 25 Sep 2020 17:24:03 |

**US3402139**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:26:34**

**Time of assessment (00:00-23:59)**

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 16:53:21 |
| User entered '13:07'      | (b) (4)            |                      |
|                           | Traci Hull (b) (4) | 25 Sep 2020 17:24:03 |
|                           | (b) (4)            |                      |

**US3402139**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:26:34**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered '25 Sep 2020 13:07' | System           | 25 Sep 2020 17:24:03 |

US3402139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:34

Temperature (xxx.x)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 16:53:21 |
| User entered '98.8' F     | Traci Hull (b) (4) | 25 Sep 2020 17:24:03 |

**US3402139**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:26:34**

[Route of measurement](#)

| Audit                      | User                                     | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                         | 27 Mar 2021 18:38:17 |
| User signature succeeded.  | Frank Eder (b) (4)                       | 15 Feb 2021 16:53:21 |
| User entered 'Oral (Oral)' | (b) (4)<br>Traci Hull (b) (4)<br>(b) (4) | 25 Sep 2020 17:24:03 |

**US3402139**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:26:34**

[If Other, specify](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                         | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)                       | 15 Feb 2021 16:53:21 |
| User entered empty.       | (b) (4)<br>Traci Hull (b) (4)<br>(b) (4) | 25 Sep 2020 17:24:03 |

**US3402139**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:26:34**

[Pulse \(xxx\)](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 16:53:21 |
| User entered '65'         | Traci Hull (b) (4) | 25 Sep 2020 17:24:03 |



**US3402139**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:26:34**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered 'bpm' | System           | 25 Sep 2020 17:24:03 |

US3402139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:34

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)              | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)            | 15 Feb 2021 16:53:21 |
| User entered '12'         | (b) (4)<br>Traci Hull (b) (4) | 25 Sep 2020 17:24:03 |

US3402139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:34

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered 'breaths/min' | System           | 25 Sep 2020 17:24:03 |

**US3402139**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:26:34**

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 16:53:21 |
| User entered '120'        | Traci Hull (b) (4) | 25 Sep 2020 17:24:03 |

**US3402139**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:26:34**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered 'mmHg' | System           | 25 Sep 2020 17:24:03 |

**US3402139**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:26:34**

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 16:53:21 |
| User entered '73'         | Traci Hull (b) (4) | 25 Sep 2020 17:24:03 |

**US3402139**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:26:34**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered 'mmHg' | System           | 25 Sep 2020 17:24:03 |

US3402139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:34

Height (derived)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
|                   |                  |                      |



US3402139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:34

Weight (derived)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
|                   |                  |                      |

**US3402139**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:26:34**

[Was the physical examination performed?](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 16:53:21 |
| User entered 'No (N)'     | (b) (4)            |                      |
|                           | Traci Hull (b) (4) | 25 Sep 2020 17:24:27 |
|                           | (b) (4)            |                      |

**US3402139**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:26:34**

**Date of examination (dd MMM yyyy)**

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 16:53:21 |
| User entered empty.       | (b) (4)            | 25 Sep 2020 17:24:27 |
|                           | Traci Hull (b) (4) |                      |
|                           | (b) (4)            |                      |

**US3402139**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:26:34**

[Was the sample collected?](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)              | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4)            | 15 Feb 2021 16:53:21 |
| User entered 'Yes (Y)'    | (b) (4)<br>Traci Hull (b) (4) | 25 Sep 2020 17:24:39 |

**US3402139**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:26:34**

**Collection date** (*dd MMM yyyy*)

| Audit                      | User               | Time (GMT)           |
|----------------------------|--------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded.  | Frank Eder (b) (4) | 15 Feb 2021 16:53:21 |
| User entered '25 Sep 2020' | (b) (4)            |                      |
|                            | Traci Hull (b) (4) | 25 Sep 2020 17:24:39 |
|                            | (b) (4)            |                      |

**US3402139**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:26:34**

[Collection time \(00:00-23:59\)](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 16:53:21 |
| User entered '13:13'      | (b) (4)            |                      |
|                           | Traci Hull (b) (4) | 25 Sep 2020 17:24:39 |
|                           | (b) (4)            |                      |

**US3402139**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:26:34**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered '25 Sep 2020 13:13' | System           | 25 Sep 2020 17:24:39 |

US3402139

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:34

[Is the participant continuing to the next visit?](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 16:53:21 |
| User entered 'Yes (Y)'    | (b) (4)            | 25 Sep 2020 17:24:44 |
|                           | Traci Hull (b) (4) |                      |
|                           | (b) (4)            |                      |



**US3402139**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:26:34**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered '1'  | System           | 25 Sep 2020 17:24:44 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.    | System           | 01 Aug 2020 14:29:27 |
| User entered 'Day 64' | System           | 01 Aug 2020 14:29:27 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-10-02T10:50:22', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'a648b738-bdc5-4c0d-806a-13767a7e9e20' | System           | 02 Oct 2020 14:50:50 |
| User entered 'No (N)'  | System           | 02 Oct 2020 14:50:50 |

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

Have you been exposed to someone with 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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-10-02T10:50:34', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'a648b738-bdc5-4c0d-806a-13767a7e9e20' | System           | 02 Oct 2020 14:50:50 |
| User entered 'No (N)'  | System           | 02 Oct 2020 14:50:50 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Date and time of submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-10-02T10:50:46', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'a648b738-bdc5-4c0d-806a-13767a7e9e20' | System           | 02 Oct 2020 14:50:50 |
| User entered '02 Oct 2020 10:50:46'  | System           | 02 Oct 2020 14:50:50 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.               | System           | 01 Aug 2020 14:29:27 |
| User entered '01 Oct 2020 00:01' | System           | 01 Aug 2020 14:29:27 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.               | System           | 01 Aug 2020 14:29:27 |
| User entered '05 Oct 2020 23:59' | System           | 01 Aug 2020 14:29:27 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.    | System           | 01 Aug 2020 14:29:27 |
| User entered 'Day 71' | System           | 01 Aug 2020 14:29:27 |



US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

[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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-10-10T07:32:05', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '4b6bb205-e0c7-4ff0-922d-ebd2bdcc34e' | System           | 10 Oct 2020 11:32:22 |
| User entered 'No (N)'   | System           | 10 Oct 2020 11:32:22 |

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

Have you been exposed to someone with 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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-10-10T07:32:12', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '4b6bb205-e0c7-4ff0-922d-ebd2bdcc34e' | System           | 10 Oct 2020 11:32:22 |
| User entered 'No (N)'   | System           | 10 Oct 2020 11:32:22 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Date and time of submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-10-10T07:32:16', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '4b6bb205-e0c7-4ff0-922d-ebcd2bdcc34e' | System           | 10 Oct 2020 11:32:22 |
| User entered '10 Oct 2020 07:32:16'  | System           | 10 Oct 2020 11:32:22 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.               | System           | 01 Aug 2020 14:29:27 |
| User entered '08 Oct 2020 00:01' | System           | 01 Aug 2020 14:29:27 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.               | System           | 01 Aug 2020 14:29:27 |
| User entered '12 Oct 2020 23:59' | System           | 01 Aug 2020 14:29:27 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.    | System           | 01 Aug 2020 14:29:27 |
| User entered 'Day 78' | System           | 01 Aug 2020 14:29:27 |

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

[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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-10-18T07:47:51', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b2c6776f-9c1a-4037-bd13-ecddc8a77dc5' | System           | 18 Oct 2020 11:48:16 |
| User entered 'No (N)'  | System           | 18 Oct 2020 11:48:16 |

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

Have you been exposed to someone with 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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-10-18T07:47:56', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b2c6776f-9c1a-4037-bd13-ecddc8a77dc5' | System           | 18 Oct 2020 11:48:16 |
| User entered 'No (N)'  | System           | 18 Oct 2020 11:48:16 |



**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Date and time of submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-10-18T07:47:59', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'b2c6776f-9c1a-4037-bd13-ecddc8a77dc5' | System           | 18 Oct 2020 11:48:16 |
| User entered '18 Oct 2020 07:47:59'  | System           | 18 Oct 2020 11:48:16 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.               | System           | 01 Aug 2020 14:29:27 |
| User entered '15 Oct 2020 00:01' | System           | 01 Aug 2020 14:29:27 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.               | System           | 01 Aug 2020 14:29:27 |
| User entered '19 Oct 2020 23:59' | System           | 01 Aug 2020 14:29:27 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.    | System           | 01 Aug 2020 14:29:27 |
| User entered 'Day 92' | System           | 01 Aug 2020 14:29:27 |

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

[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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-10-30T10:04:04', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '2c74702c-9abb-46ba-af9e-43e2f466a92b' | System           | 30 Oct 2020 14:04:14 |
| User entered 'No (N)'  | System           | 30 Oct 2020 14:04:14 |

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

Have you been exposed to someone with 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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-10-30T10:04:08', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '2c74702c-9abb-46ba-af9e-43e2f466a92b' | System           | 30 Oct 2020 14:04:14 |
| User entered 'No (N)'  | System           | 30 Oct 2020 14:04:14 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Date and time of submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-10-30T10:04:11', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '2c74702c-9abb-46ba-af9e-43e2f466a92b' | System           | 30 Oct 2020 14:04:14 |
| User entered '30 Oct 2020 10:04:11'  | System           | 30 Oct 2020 14:04:14 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.               | System           | 01 Aug 2020 14:29:27 |
| User entered '29 Oct 2020 00:01' | System           | 01 Aug 2020 14:29:27 |



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**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.               | System           | 01 Aug 2020 14:29:27 |
| User entered '02 Nov 2020 23:59' | System           | 01 Aug 2020 14:29:27 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.    | System           | 01 Aug 2020 14:29:27 |
| User entered 'Day 99' | System           | 01 Aug 2020 14:29:27 |

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

[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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-11-07T07:42:55', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '6cdf2592-0bb0-4afd-8d48-3996193d6d0e' | System           | 07 Nov 2020 12:43:20 |
| User entered 'No (N)'  | System           | 07 Nov 2020 12:43:20 |

US3402139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:34

Have you been exposed to someone with 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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-11-07T07:43:13', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '6cdf2592-0bb0-4afd-8d48-3996193d6d0e' | System           | 07 Nov 2020 12:43:20 |
| User entered 'No (N)'  | System           | 07 Nov 2020 12:43:20 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Date and time of submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-11-07T07:43:15', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '6cdf2592-0bb0-4afd-8d48-3996193d6d0e' | System           | 07 Nov 2020 12:43:20 |
| User entered '07 Nov 2020 07:43:15'  | System           | 07 Nov 2020 12:43:20 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.               | System           | 01 Aug 2020 14:29:27 |
| User entered '05 Nov 2020 00:01' | System           | 01 Aug 2020 14:29:27 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.               | System           | 01 Aug 2020 14:29:27 |
| User entered '09 Nov 2020 23:59' | System           | 01 Aug 2020 14:29:27 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| Data hard locked.      | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.     | System           | 01 Aug 2020 14:29:27 |
| User entered 'Day 106' | System           | 01 Aug 2020 14:29:27 |



**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-11-16T16:53:03', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '0a405e48-56f8-4d6c-a188-980aff92d114' | System           | 16 Nov 2020 21:53:17 |
| User entered 'No (N)'  | System           | 16 Nov 2020 21:53:17 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

Have you been exposed to someone with 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 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-11-16T16:53:10', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '0a405e48-56f8-4d6c-a188-980aff92d114' | System           | 16 Nov 2020 21:53:17 |
| User entered 'No (N)'  | System           | 16 Nov 2020 21:53:17 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Date and time of submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f0935be7a2d5bf5d)', Time: '2020-11-16T16:53:13', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '0a405e48-56f8-4d6c-a188-980aff92d114' | System           | 16 Nov 2020 21:53:17 |
| User entered '16 Nov 2020 16:53:13'  | System           | 16 Nov 2020 21:53:17 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.               | System           | 01 Aug 2020 14:29:27 |
| User entered '12 Nov 2020 00:01' | System           | 01 Aug 2020 14:29:27 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 03:55:53 |
| Data entry locked.               | System           | 01 Aug 2020 14:29:27 |
| User entered '16 Nov 2020 23:59' | System           | 01 Aug 2020 14:29:27 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 26 Apr 2021 06:34:48 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 11:17:15 |
| Data entry locked.                        | System           | 01 Aug 2020 14:29:27 |
| User entered 'Day 113'                    | System           | 01 Aug 2020 14:29:27 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 26 Apr 2021 06:34:48 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 26 Apr 2021 06:34:48 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 11:17:15 |



**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 26 Apr 2021 06:34:48 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 26 Apr 2021 06:34:48 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Fever \(Temperature  \$\geq\$  100.4°F/38°C\)](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 26 Apr 2021 06:34:48 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Chills](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 26 Apr 2021 06:34:48 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Cough](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 26 Apr 2021 06:34:48 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Shortness of breath](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 26 Apr 2021 06:34:48 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Difficulty breathing](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 26 Apr 2021 06:34:48 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Fatigue](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 26 Apr 2021 06:34:48 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 11:17:15 |



**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Muscle aches](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 26 Apr 2021 06:34:48 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Body aches](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 26 Apr 2021 06:34:48 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Headache](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 26 Apr 2021 06:34:48 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[New loss of taste](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 26 Apr 2021 06:34:48 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[New loss of smell](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 26 Apr 2021 06:34:48 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Sore throat](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 26 Apr 2021 06:34:48 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Congestion](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 26 Apr 2021 06:34:48 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Runny nose](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 26 Apr 2021 06:34:48 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 11:17:15 |



**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Nausea](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 26 Apr 2021 06:34:48 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Vomiting](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 26 Apr 2021 06:34:48 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Diarrhea](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 26 Apr 2021 06:34:48 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 26 Apr 2021 06:34:48 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 26 Apr 2021 06:34:48 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 26 Apr 2021 06:34:48 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Date and time of submission](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 26 Apr 2021 06:34:48 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 26 Apr 2021 06:34:48 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 11:17:15 |
| Data entry locked.                        | System           | 01 Aug 2020 14:29:27 |
| User entered '19 Nov 2020 00:01'          | System           | 01 Aug 2020 14:29:27 |



**US3402139**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Close Date & Time](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 26 Apr 2021 06:34:48 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 11:17:15 |
| Data entry locked.                        | System           | 01 Aug 2020 14:29:27 |
| User entered '23 Nov 2020 23:59'          | System           | 01 Aug 2020 14:29:27 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2020-11-19T16:50:51', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '413a93b5-d68c-4cc7-b34e-d785b628697e' | System | 19 Nov 2020 21:51:04 |
| User entered 'No (N)'  | System | 19 Nov 2020 21:51:04 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2020-11-19T16:50:56', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '413a93b5-d68c-4cc7-b34e-d785b628697e' | System | 19 Nov 2020 21:51:04 |
| User entered 'No (N)'  | System | 19 Nov 2020 21:51:04 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2020-11-19T16:50:59', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '413a93b5-d68c-4cc7-b34e-d785b628697e' | System | 19 Nov 2020 21:51:04 |
| User entered '19 Nov 2020 16:50:59'  | System | 19 Nov 2020 21:51:04 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '16 Nov 2020 00:01' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '20 Nov 2020 23:59' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 11:17:15 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2020-11-25T13:26:44', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'edecea1d-8481-4bd5-a13f-a0631ed0eb9b' | System | 25 Nov 2020 18:26:52 |
| User entered 'No (N)'  | System | 25 Nov 2020 18:26:52 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2020-11-25T13:26:46', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'edecea1d-8481-4bd5-a13f-a0631ed0eb9b' | System | 25 Nov 2020 18:26:52 |
| User entered 'No (N)'  | System | 25 Nov 2020 18:26:52 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2020-11-25T13:26:50', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'edecea1d-8481-4bd5-a13f-a0631ed0eb9b' User entered '25 Nov 2020 13:26:50' | System | 25 Nov 2020 18:26:52 |
|  | System | 25 Nov 2020 18:26:52 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '23 Nov 2020 00:01' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '27 Nov 2020 23:59' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2020-12-04T14:08:05', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '1688da78-b3ae-43cb-8ad5-670f3d2dd6d5' | System | 04 Dec 2020 19:08:17 |
| User entered 'No (N)'  | System | 04 Dec 2020 19:08:17 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2020-12-04T14:08:11', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '1688da78-b3ae-43cb-8ad5-670f3d2dd6d5' | System | 04 Dec 2020 19:08:17 |
| User entered 'No (N)'  | System | 04 Dec 2020 19:08:17 |



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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:26:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2020-12-04T14:08:13', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '1688da78-b3ae-43cb-8ad5-670f3d2dd6d5' | System | 04 Dec 2020 19:08:17 |
| User entered '04 Dec 2020 14:08:13'  | System | 04 Dec 2020 19:08:17 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '30 Nov 2020 00:01' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '04 Dec 2020 23:59' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '07 Dec 2020 00:01' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '11 Dec 2020 23:59' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2020-12-14T15:37:17', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '85172243-5db8-4e7b-9f65-614ad11ab1b8' | System | 14 Dec 2020 20:37:53 |
| User entered 'No (N)'  | System | 14 Dec 2020 20:37:53 |



**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2020-12-14T15:37:28', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '85172243-5db8-4e7b-9f65-614ad11ab1b8' | System | 14 Dec 2020 20:37:53 |
| User entered 'Yes (Y)'   | System | 14 Dec 2020 20:37:53 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2020-12-14T15:37:39', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '85172243-5db8-4e7b-9f65-614ad11ab1b8' | System | 14 Dec 2020 20:37:53 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)'   | System | 14 Dec 2020 20:37:53 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2020-12-14T15:37:43', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '85172243-5db8-4e7b-9f65-614ad11ab1b8' User entered '14 Dec 2020 15:37:43' | System | 14 Dec 2020 20:37:53 |
|  | System | 14 Dec 2020 20:37:53 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '14 Dec 2020 00:01' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '18 Dec 2020 23:59' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '21 Dec 2020 00:01' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '25 Dec 2020 23:59' | System | 19 Nov 2020 11:17:15 |



**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2020-12-28T12:27:06', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '00569f93-11f0-4679-b2d1-346e576b7b2b' | System | 28 Dec 2020 17:27:16 |
| User entered 'No (N)'  | System | 28 Dec 2020 17:27:16 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2020-12-28T12:27:09', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '00569f93-11f0-4679-b2d1-346e576b7b2b' | System | 28 Dec 2020 17:27:16 |
| User entered 'No (N)'  | System | 28 Dec 2020 17:27:16 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2020-12-28T12:27:12', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '00569f93-11f0-4679-b2d1-346e576b7b2b' User entered '28 Dec 2020 12:27:12' | System | 28 Dec 2020 17:27:16 |
|  | System | 28 Dec 2020 17:27:16 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '28 Dec 2020 00:01' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '01 Jan 2021 23:59' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-01-07T18:54:54', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '38aded94-7c4a-4c47-b89b-eecfd4a30713' | System | 07 Jan 2021 23:55:07 |
| User entered 'No (N)'  | System | 07 Jan 2021 23:55:07 |



**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-01-07T18:54:59', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '38aded94-7c4a-4c47-b89b-eecfd4a30713' | System | 07 Jan 2021 23:55:07 |
| User entered 'No (N)'  | System | 07 Jan 2021 23:55:07 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-01-07T18:55:03', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '38aded94-7c4a-4c47-b89b-eecfd4a30713' User entered '07 Jan 2021 18:55:03' | System | 07 Jan 2021 23:55:07 |
|  | System | 07 Jan 2021 23:55:07 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '04 Jan 2021 00:01' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '08 Jan 2021 23:59' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-01-11T08:48:58', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'f0171245-10ad-4c29-b7f0-18a28833775c' | System | 11 Jan 2021 13:49:12 |
| User entered 'No (N)'  | System | 11 Jan 2021 13:49:12 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-01-11T08:49:03', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'f0171245-10ad-4c29-b7f0-18a28833775c' | System | 11 Jan 2021 13:49:12 |
| User entered 'No (N)'  | System | 11 Jan 2021 13:49:12 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-01-11T08:49:09', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'f0171245-10ad-4c29-b7f0-18a28833775c' | System | 11 Jan 2021 13:49:12 |
| User entered '11 Jan 2021 08:49:09'  | System | 11 Jan 2021 13:49:12 |



**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '11 Jan 2021 00:01' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '15 Jan 2021 23:59' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-01-20T08:28:15', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '162a0b6d-687f-4cd4-acdf-951dc5a3b97e' | System | 20 Jan 2021 13:28:24 |
| User entered 'No (N)'  | System | 20 Jan 2021 13:28:24 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-01-20T08:28:19', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '162a0b6d-687f-4cd4-acdf-951dc5a3b97e' | System | 20 Jan 2021 13:28:24 |
| User entered 'No (N)'  | System | 20 Jan 2021 13:28:24 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-01-20T08:28:22', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '162a0b6d-687f-4cd4-acdf-951dc5a3b97e' User entered '20 Jan 2021 08:28:22' | System | 20 Jan 2021 13:28:24 |
|  | System | 20 Jan 2021 13:28:24 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '18 Jan 2021 00:01' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '22 Jan 2021 23:59' | System | 19 Nov 2020 11:17:15 |



**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-01-27T12:49:06', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'a63ac259-5c41-4972-8249-a90e7e2ff2a0' | System | 27 Jan 2021 17:49:17 |
| User entered 'No (N)'  | System | 27 Jan 2021 17:49:17 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-01-27T12:49:12', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'a63ac259-5c41-4972-8249-a90e7e2ff2a0' | System | 27 Jan 2021 17:49:17 |
| User entered 'No (N)'  | System | 27 Jan 2021 17:49:17 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-01-27T12:49:15', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'a63ac259-5c41-4972-8249-a90e7e2ff2a0' | System | 27 Jan 2021 17:49:17 |
| User entered '27 Jan 2021 12:49:15'  | System | 27 Jan 2021 17:49:17 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '25 Jan 2021 00:01' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '29 Jan 2021 23:59' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-02-05T14:00:45', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'c0c290c3-6ef8-4856-a831-95dfc52d4514' | System | 05 Feb 2021 19:00:55 |
| User entered 'No (N)'  | System | 05 Feb 2021 19:00:55 |



**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-02-05T14:00:48', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'c0c290c3-6ef8-4856-a831-95dfc52d4514' | System | 05 Feb 2021 19:00:55 |
| User entered 'No (N)'  | System | 05 Feb 2021 19:00:55 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-02-05T14:00:51', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'c0c290c3-6ef8-4856-a831-95dfc52d4514' | System | 05 Feb 2021 19:00:55 |
| User entered '05 Feb 2021 14:00:51'  | System | 05 Feb 2021 19:00:55 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '01 Feb 2021 00:01' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '05 Feb 2021 23:59' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-02-11T07:10:25', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '4166addb-4a5d-46f7-b129-4c53e927dbb7' | System | 11 Feb 2021 12:10:34 |
| User entered 'No (N)'  | System | 11 Feb 2021 12:10:34 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-02-11T07:10:28', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '4166addb-4a5d-46f7-b129-4c53e927dbb7' | System | 11 Feb 2021 12:10:34 |
| User entered 'No (N)'  | System | 11 Feb 2021 12:10:34 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

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| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-02-11T07:10:31', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '4166addb-4a5d-46f7-b129-4c53e927dbb7' | System | 11 Feb 2021 12:10:34 |
| User entered '11 Feb 2021 07:10:31'  | System | 11 Feb 2021 12:10:34 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '08 Feb 2021 00:01' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '12 Feb 2021 23:59' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-02-19T10:21:20', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '0075c301-3340-4a03-a105-5b3487cb03de' | System | 19 Feb 2021 15:21:28 |
| User entered 'No (N)'  | System | 19 Feb 2021 15:21:28 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-02-19T10:21:23', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '0075c301-3340-4a03-a105-5b3487cb03de' | System | 19 Feb 2021 15:21:28 |
| User entered 'No (N)'  | System | 19 Feb 2021 15:21:28 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-02-19T10:21:25', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '0075c301-3340-4a03-a105-5b3487cb03de' | System | 19 Feb 2021 15:21:28 |
| User entered '19 Feb 2021 10:21:25'  | System | 19 Feb 2021 15:21:28 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '15 Feb 2021 00:01' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '19 Feb 2021 23:59' | System | 19 Nov 2020 11:17:15 |



**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '22 Feb 2021 00:01' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '26 Feb 2021 23:59' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-03-01T09:31:59-05:00', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'd848c150-e67f-455a-bf9a-bf757c4c58b1' | System | 01 Mar 2021 14:32:09 |
| User entered 'No (N)'  | System | 01 Mar 2021 14:32:09 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-03-01T09:32:01-05:00', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'd848c150-e67f-455a-bf9a-bf757c4c58b1' | System | 01 Mar 2021 14:32:09 |
| User entered 'No (N)'  | System | 01 Mar 2021 14:32:09 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-03-01T09:32:04-05:00', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'd848c150-e67f-455a-bf9a-bf757c4c58b1' User entered '01 Mar 2021 09:32:04' | System | 01 Mar 2021 14:32:09 |
|  | System | 01 Mar 2021 14:32:09 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '01 Mar 2021 00:01' | System | 19 Nov 2020 11:17:15 |



**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '05 Mar 2021 23:59' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-03-10T09:25:59-05:00', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'a6056574-4abf-49c5-8100-eed086f91015' | System | 10 Mar 2021 14:26:12 |
| User entered 'No (N)'  | System | 10 Mar 2021 14:26:12 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-03-10T09:26:01-05:00', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'a6056574-4abf-49c5-8100-eed086f91015' | System | 10 Mar 2021 14:26:12 |
| User entered 'No (N)'  | System | 10 Mar 2021 14:26:12 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-03-10T09:26:04-05:00', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'a6056574-4abf-49c5-8100-eed086f91015' User entered '10 Mar 2021 09:26:04' | System | 10 Mar 2021 14:26:12 |
|  | System | 10 Mar 2021 14:26:12 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '08 Mar 2021 00:01' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '12 Mar 2021 23:59' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 11:17:15 |



**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-03-15T08:05:44-04:00', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'a548f94f-4e2c-450b-acb3-f7bf4d161dda' User entered 'No (N)' | System | 15 Mar 2021 12:05:54 |
|  | System | 15 Mar 2021 12:05:54 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-03-15T08:05:48-04:00', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'a548f94f-4e2c-450b-acb3-f7bf4d161dda' User entered 'No (N)' | System | 15 Mar 2021 12:05:54 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-03-15T08:05:50-04:00', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'a548f94f-4e2c-450b-acb3-f7bf4d161dda' User entered '15 Mar 2021 08:05:50' | System | 15 Mar 2021 12:05:54 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '15 Mar 2021 00:01' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '19 Mar 2021 23:59' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-03-25T08:51:19-04:00', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '9d8d3165-0024-4939-8a96-3810026a1ead' | System | 25 Mar 2021 12:51:33 |
| User entered 'No (N)'  | System | 25 Mar 2021 12:51:33 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-03-25T08:51:26-04:00', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '9d8d3165-0024-4939-8a96-3810026a1ead' | System | 25 Mar 2021 12:51:33 |
| User entered 'No (N)'  | System | 25 Mar 2021 12:51:33 |



**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-03-25T08:51:28-04:00', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '9d8d3165-0024-4939-8a96-3810026a1ead' User entered '25 Mar 2021 08:51:28' | System | 25 Mar 2021 12:51:33 |
|  | System | 25 Mar 2021 12:51:33 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '22 Mar 2021 00:01' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '26 Mar 2021 23:59' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-03-29T16:36:47-04:00', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'e7554d66-a757-4e82-a450-b8d1a4e89f41' | System | 29 Mar 2021 20:36:57 |
| User entered 'No (N)'  | System | 29 Mar 2021 20:36:57 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-03-29T16:36:48-04:00', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'e7554d66-a757-4e82-a450-b8d1a4e89f41' | System | 29 Mar 2021 20:36:57 |
| User entered 'No (N)'  | System | 29 Mar 2021 20:36:57 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-03-29T16:36:51-04:00', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'e7554d66-a757-4e82-a450-b8d1a4e89f41' User entered '29 Mar 2021 16:36:51' | System | 29 Mar 2021 20:36:57 |
|  | System | 29 Mar 2021 20:36:57 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '29 Mar 2021 00:01' | System | 19 Nov 2020 11:17:15 |



**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '02 Apr 2021 23:59' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-04-08T10:50:33-04:00', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '2c63033e-1fed-4fc6-a485-965f2fb1aa20' User entered 'No (N)' | System | 08 Apr 2021 14:50:41 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-04-08T10:50:35-04:00', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '2c63033e-1fed-4fc6-a485-965f2fb1aa20' | System | 08 Apr 2021 14:50:41 |
| User entered 'No (N)'  | System | 08 Apr 2021 14:50:41 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-04-08T10:50:37-04:00', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '2c63033e-1fed-4fc6-a485-965f2fb1aa20' User entered '08 Apr 2021 10:50:37' | System | 08 Apr 2021 14:50:41 |
|  | System | 08 Apr 2021 14:50:41 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '05 Apr 2021 00:01' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '09 Apr 2021 23:59' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 11:17:15 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-04-12T15:22:43-04:00', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'c4e7a847-4d6b-445b-a2db-0a479dc91eab' User entered 'No (N)' | System | 12 Apr 2021 19:22:53 |
|  | System | 12 Apr 2021 19:22:53 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-04-12T15:22:45-04:00', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'c4e7a847-4d6b-445b-a2db-0a479dc91eab' | System | 12 Apr 2021 19:22:53 |
| User entered 'No (N)'  | System | 12 Apr 2021 19:22:53 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-04-12T15:22:48-04:00', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'c4e7a847-4d6b-445b-a2db-0a479dc91eab' User entered '12 Apr 2021 15:22:48' | System | 12 Apr 2021 19:22:53 |
|  | System | 12 Apr 2021 19:22:53 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '12 Apr 2021 00:01' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '16 Apr 2021 23:59' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-04-22T06:52:07-04:00', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'e5259c9f-d2d6-43fb-92dc-47cef7f5a554' | System | 22 Apr 2021 10:52:16 |
| User entered 'No (N)'  | System | 22 Apr 2021 10:52:16 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-04-22T06:52:08-04:00', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'e5259c9f-d2d6-43fb-92dc-47cef7f5a554' | System | 22 Apr 2021 10:52:16 |
| User entered 'No (N)'  | System | 22 Apr 2021 10:52:16 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-04-22T06:52:11-04:00', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: 'e5259c9f-d2d6-43fb-92dc-47cef7f5a554' | System | 22 Apr 2021 10:52:16 |
| User entered '22 Apr 2021 06:52:11'  | System | 22 Apr 2021 10:52:16 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '19 Apr 2021 00:01' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '23 Apr 2021 23:59' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-04-29T07:51:10-04:00', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '83ad845c-a957-46dd-9d83-25f6b0d79c46' | System | 29 Apr 2021 11:51:19 |
| User entered 'No (N)'  | System | 29 Apr 2021 11:51:19 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-04-29T07:51:11-04:00', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '83ad845c-a957-46dd-9d83-25f6b0d79c46' | System | 29 Apr 2021 11:51:19 |
| User entered 'No (N)'  | System | 29 Apr 2021 11:51:19 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:26:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-04-29T07:51:14-04:00', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '83ad845c-a957-46dd-9d83-25f6b0d79c46' | System | 29 Apr 2021 11:51:19 |
| User entered '29 Apr 2021 07:51:14'  | System | 29 Apr 2021 11:51:19 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '26 Apr 2021 00:01' | System | 19 Nov 2020 11:17:15 |



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**Folder: New Safety Follow Up Diary (1)**

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[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '30 Apr 2021 23:59' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '03 May 2021 00:01' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '07 May 2021 23:59' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '10 May 2021 00:01' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

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[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '14 May 2021 23:59' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 11:17:15 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '17 May 2021 00:01' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '21 May 2021 23:59' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '24 May 2021 00:01' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '28 May 2021 23:59' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '31 May 2021 00:01' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '04 Jun 2021 23:59' | System | 19 Nov 2020 11:17:15 |



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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '07 Jun 2021 00:01' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '11 Jun 2021 23:59' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '14 Jun 2021 00:01' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '18 Jun 2021 23:59' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '21 Jun 2021 00:01' | System | 19 Nov 2020 11:17:15 |



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**Folder: New Safety Follow Up Diary (1)**

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[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '25 Jun 2021 23:59' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '28 Jun 2021 00:01' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '02 Jul 2021 23:59' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '05 Jul 2021 00:01' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '09 Jul 2021 23:59' | System | 19 Nov 2020 11:17:15 |

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 11:17:15 |



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**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '12 Jul 2021 00:01' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:26:34**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '16 Jul 2021 23:59' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '19 Jul 2021 00:01' | System | 19 Nov 2020 11:17:15 |

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**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '23 Jul 2021 23:59' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '26 Jul 2021 00:01' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '30 Jul 2021 23:59' | System | 19 Nov 2020 11:17:15 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '02 Aug 2021 00:01' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '06 Aug 2021 23:59' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '09 Aug 2021 00:01' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '13 Aug 2021 23:59' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '16 Aug 2021 00:01' | System | 19 Nov 2020 11:17:15 |



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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:26:34**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '20 Aug 2021 23:59' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '23 Aug 2021 00:01' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '27 Aug 2021 23:59' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

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[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '30 Aug 2021 00:01' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '03 Sep 2021 23:59' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 11:17:15 |



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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:26:34**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '06 Sep 2021 00:01' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '10 Sep 2021 23:59' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '13 Sep 2021 00:01' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '17 Sep 2021 23:59' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '20 Sep 2021 00:01' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '24 Sep 2021 23:59' | System | 19 Nov 2020 11:17:15 |



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**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '27 Sep 2021 00:01' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '01 Oct 2021 23:59' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '04 Oct 2021 00:01' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:26:34**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '08 Oct 2021 23:59' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '11 Oct 2021 00:01' | System | 19 Nov 2020 11:17:15 |



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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '15 Oct 2021 23:59' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '18 Oct 2021 00:01' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '22 Oct 2021 23:59' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '25 Oct 2021 00:01' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '29 Oct 2021 23:59' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 11:17:15 |



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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '01 Nov 2021 00:01' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '05 Nov 2021 23:59' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '08 Nov 2021 00:01' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '12 Nov 2021 23:59' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '15 Nov 2021 00:01' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '19 Nov 2021 23:59' | System | 19 Nov 2020 11:17:15 |



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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '22 Nov 2021 00:01' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '26 Nov 2021 23:59' | System | 19 Nov 2020 11:17:15 |

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '29 Nov 2021 00:01' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '03 Dec 2021 23:59' | System | 19 Nov 2020 11:17:15 |

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| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '06 Dec 2021 00:01' | System | 19 Nov 2020 11:17:15 |



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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '10 Dec 2021 23:59' | System | 19 Nov 2020 11:17:15 |

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '13 Dec 2021 00:01' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '17 Dec 2021 23:59' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '20 Dec 2021 00:01' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '24 Dec 2021 23:59' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 11:17:15 |



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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '27 Dec 2021 00:01' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '31 Dec 2021 23:59' | System | 19 Nov 2020 11:17:15 |

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**Form: Safety Follow Up Diary**

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '03 Jan 2022 00:01' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '07 Jan 2022 23:59' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '10 Jan 2022 00:01' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '14 Jan 2022 23:59' | System | 19 Nov 2020 11:17:15 |



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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 11:17:15 |

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**Form: Safety Follow Up Diary**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '17 Jan 2022 00:01' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '21 Jan 2022 23:59' | System | 19 Nov 2020 11:17:15 |

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '24 Jan 2022 00:01' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '28 Jan 2022 23:59' | System | 19 Nov 2020 11:17:15 |

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**Form: Safety Follow Up Diary**

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '31 Jan 2022 00:01' | System | 19 Nov 2020 11:17:15 |



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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '04 Feb 2022 23:59' | System | 19 Nov 2020 11:17:15 |

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| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '07 Feb 2022 00:01' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '11 Feb 2022 23:59' | System | 19 Nov 2020 11:17:15 |

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| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '14 Feb 2022 00:01' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '18 Feb 2022 23:59' | System | 19 Nov 2020 11:17:15 |

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| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 11:17:15 |



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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '21 Feb 2022 00:01' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '25 Feb 2022 23:59' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '28 Feb 2022 00:01' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '04 Mar 2022 23:59' | System | 19 Nov 2020 11:17:15 |

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**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '07 Mar 2022 00:01' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '11 Mar 2022 23:59' | System | 19 Nov 2020 11:17:15 |



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| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '14 Mar 2022 00:01' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '18 Mar 2022 23:59' | System | 19 Nov 2020 11:17:15 |

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| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '21 Mar 2022 00:01' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '25 Mar 2022 23:59' | System | 19 Nov 2020 11:17:15 |

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '28 Mar 2022 00:01' | System | 19 Nov 2020 11:17:15 |



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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '01 Apr 2022 23:59' | System | 19 Nov 2020 11:17:15 |

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| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '04 Apr 2022 00:01' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '08 Apr 2022 23:59' | System | 19 Nov 2020 11:17:15 |

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| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '11 Apr 2022 00:01' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '15 Apr 2022 23:59' | System | 19 Nov 2020 11:17:15 |

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| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 11:17:15 |



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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '18 Apr 2022 00:01' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '22 Apr 2022 23:59' | System | 19 Nov 2020 11:17:15 |

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| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '25 Apr 2022 00:01' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '29 Apr 2022 23:59' | System | 19 Nov 2020 11:17:15 |

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| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '02 May 2022 00:01' | System | 19 Nov 2020 11:17:15 |

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**Form: Safety Follow Up Diary**

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[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '06 May 2022 23:59' | System | 19 Nov 2020 11:17:15 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '09 May 2022 00:01' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '13 May 2022 23:59' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '16 May 2022 00:01' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '20 May 2022 23:59' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '23 May 2022 00:01' | System | 19 Nov 2020 11:17:15 |



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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '27 May 2022 23:59' | System | 19 Nov 2020 11:17:15 |

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| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '30 May 2022 00:01' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '03 Jun 2022 23:59' | System | 19 Nov 2020 11:17:15 |

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| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '06 Jun 2022 00:01' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '10 Jun 2022 23:59' | System | 19 Nov 2020 11:17:15 |

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| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 11:17:15 |



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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '13 Jun 2022 00:01' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '17 Jun 2022 23:59' | System | 19 Nov 2020 11:17:15 |

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| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '20 Jun 2022 00:01' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '24 Jun 2022 23:59' | System | 19 Nov 2020 11:17:15 |

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '27 Jun 2022 00:01' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '01 Jul 2022 23:59' | System | 19 Nov 2020 11:17:15 |



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| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '04 Jul 2022 00:01' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '08 Jul 2022 23:59' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '11 Jul 2022 00:01' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '15 Jul 2022 23:59' | System | 19 Nov 2020 11:17:15 |

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| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '18 Jul 2022 00:01' | System | 19 Nov 2020 11:17:15 |



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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '22 Jul 2022 23:59' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '25 Jul 2022 00:01' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '29 Jul 2022 23:59' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '01 Aug 2022 00:01' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '05 Aug 2022 23:59' | System | 19 Nov 2020 11:17:15 |

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| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 11:17:15 |



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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '08 Aug 2022 00:01' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '12 Aug 2022 23:59' | System | 19 Nov 2020 11:17:15 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '15 Aug 2022 00:01' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '19 Aug 2022 23:59' | System | 19 Nov 2020 11:17:15 |

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| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '22 Aug 2022 00:01' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '26 Aug 2022 23:59' | System | 19 Nov 2020 11:17:15 |



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| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '29 Aug 2022 00:01' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '02 Sep 2022 23:59' | System | 19 Nov 2020 11:17:15 |

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '05 Sep 2022 00:01' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '09 Sep 2022 23:59' | System | 19 Nov 2020 11:17:15 |

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| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '12 Sep 2022 00:01' | System | 19 Nov 2020 11:17:15 |



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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '16 Sep 2022 23:59' | System | 19 Nov 2020 11:17:15 |

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '19 Sep 2022 00:01' | System | 19 Nov 2020 11:17:15 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '23 Sep 2022 23:59' | System | 19 Nov 2020 11:17:15 |

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '26 Sep 2022 00:01' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '30 Sep 2022 23:59' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 11:17:15 |



**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '03 Oct 2022 00:01' | System | 19 Nov 2020 11:17:15 |

**US3402139**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:26:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 11:17:15 |
| Amendment Manager: User entered '07 Oct 2022 23:59' | System | 19 Nov 2020 11:17:15 |

US3402139

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:26:34**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 26 Apr 2021 06:34:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-03-01T09:32:14-05:00', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '2626c30d-2051-4c78-9c82-1251dc9fb58e' | System           | 01 Mar 2021 14:32:27 |
| User entered 'No (N)'  | System           | 01 Mar 2021 14:32:27 |

**US3402139**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:26:34**

[Date & Time of Submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 26 Apr 2021 06:34:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a05f4ca97dbea170)', Time: '2021-03-01T09:32:20-05:00', User OID: 'PatientReportedOutcome (US3402139)', ODM File OID: '2626c30d-2051-4c78-9c82-1251dc9fb58e' | System           | 01 Mar 2021 14:32:27 |
| User entered '01 Mar 2021 09:32:20'  | System           | 01 Mar 2021 14:32:27 |

**US3402139**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

[Was Contact Attempted?](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Mar 2021 22:16:31 |
| User entered 'Yes (Y)'    | (b) (4)            | 27 Nov 2020 20:25:34 |
|                           | Traci Hull (b) (4) |                      |
|                           | (b) (4)            |                      |

**US3402139**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                      | User               | Time (GMT)           |
|----------------------------|--------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded.  | Frank Eder (b) (4) | 08 Mar 2021 22:16:31 |
| User entered '26 Oct 2020' | Traci Hull (b) (4) | 27 Nov 2020 20:25:34 |

**US3402139**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

[Please select one status for the follow-up contact](#)

| Audit                                      | User               | Time (GMT)           |
|--|--------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded.                  | Frank Eder (b) (4) | 08 Mar 2021 22:16:31 |
| User entered 'Contact Made (CONTACT MADE)' | Traci Hull (b) (4) | 27 Nov 2020 20:25:34 |

**US3402139**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Mar 2021 22:16:31 |
| User entered empty.       | Traci Hull (b) (4) | 27 Nov 2020 20:25:34 |



**US3402139**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:26:34**

[Is the participant continuing to the next visit?](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 27 Mar 2021 18:38:17 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Mar 2021 22:16:31 |
| User entered 'Yes (Y)'    | Traci Hull (b) (4) | 27 Nov 2020 20:25:40 |

**US3402139**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:26:34**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:38:17 |
| User entered 'I'  | System           | 27 Nov 2020 20:25:40 |

**US3402139**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

[Was Contact Attempted?](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)              | 28 Apr 2021 05:28:07 |
| User signature succeeded. | Frank Eder (b) (4)            | 26 Apr 2021 01:45:47 |
| User entered 'Yes (Y)'    | (b) (4)<br>Traci Hull (b) (4) | 27 Nov 2020 20:25:54 |

**US3402139**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)              | 28 Apr 2021 05:28:07 |
| User signature succeeded.  | Frank Eder (b) (4)            | 26 Apr 2021 01:45:47 |
| User entered '27 Nov 2020' | (b) (4)<br>Traci Hull (b) (4) | 27 Nov 2020 20:25:54 |

**US3402139**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                          | Time (GMT)           |
|--|-------------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)              | 28 Apr 2021 05:28:07 |
| User signature succeeded.                  | Frank Eder (b) (4)            | 26 Apr 2021 01:45:47 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Traci Hull (b) (4) | 27 Nov 2020 20:25:54 |

**US3402139**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 28 Apr 2021 05:28:07 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| User entered empty.       | (b) (4)            | 27 Nov 2020 20:25:54 |
|                           | Traci Hull (b) (4) |                      |
|                           | (b) (4)            |                      |

**US3402139**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:26:34**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)              | 28 Apr 2021 05:28:07 |
| User signature succeeded. | Frank Eder (b) (4)            | 26 Apr 2021 01:45:47 |
| User entered 'Yes (Y)'    | (b) (4)<br>Traci Hull (b) (4) | 27 Nov 2020 20:25:59 |

**US3402139**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:26:34**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 05:28:07 |
| User entered 'I'  | System           | 27 Nov 2020 20:25:59 |



**US3402139**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

[Was Contact Attempted?](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)              | 28 Apr 2021 05:28:07 |
| User signature succeeded. | Frank Eder (b) (4)            | 26 Apr 2021 01:45:47 |
| User entered 'Yes (Y)'    | (b) (4)<br>Traci Hull (b) (4) | 28 Dec 2020 17:55:43 |

**US3402139**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                      | User                          | Time (GMT)           |
|----------------------------|-------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)              | 28 Apr 2021 05:28:07 |
| User signature succeeded.  | Frank Eder (b) (4)            | 26 Apr 2021 01:45:47 |
| User entered '28 Dec 2020' | (b) (4)<br>Traci Hull (b) (4) | 28 Dec 2020 17:55:43 |

**US3402139**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                          | Time (GMT)           |
|--|-------------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)              | 28 Apr 2021 05:28:07 |
| User signature succeeded.                  | Frank Eder (b) (4)            | 26 Apr 2021 01:45:47 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Traci Hull (b) (4) | 28 Dec 2020 17:55:43 |

**US3402139**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 28 Apr 2021 05:28:07 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| User entered empty.       | (b) (4)            | 28 Dec 2020 17:55:43 |
|                           | Traci Hull (b) (4) |                      |
|                           | (b) (4)            |                      |

**US3402139**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:26:34**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)              | 28 Apr 2021 05:28:07 |
| User signature succeeded. | Frank Eder (b) (4)            | 26 Apr 2021 01:45:47 |
| User entered 'Yes (Y)'    | (b) (4)<br>Traci Hull (b) (4) | 28 Dec 2020 17:55:29 |

**US3402139**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:26:34**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 05:28:07 |
| User entered 'I'  | System           | 28 Dec 2020 17:55:29 |

**US3402139**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

[Was Contact Attempted?](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)              | 28 Apr 2021 05:28:07 |
| User signature succeeded. | Frank Eder (b) (4)            | 26 Apr 2021 01:45:47 |
| User entered 'Yes (Y)'    | (b) (4)<br>Traci Hull (b) (4) | 22 Feb 2021 13:52:06 |

**US3402139**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                      | User               | Time (GMT)           |
|----------------------------|--------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)   | 28 Apr 2021 05:28:07 |
| User signature succeeded.  | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| User entered '29 Jan 2021' | Traci Hull (b) (4) | 22 Feb 2021 13:52:06 |



**US3402139**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                          | Time (GMT)           |
|--|-------------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)              | 28 Apr 2021 05:28:07 |
| User signature succeeded.                  | Frank Eder (b) (4)            | 26 Apr 2021 01:45:47 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Traci Hull (b) (4) | 22 Feb 2021 13:52:06 |

**US3402139**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 28 Apr 2021 05:28:07 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| User entered empty.       | (b) (4)            | 22 Feb 2021 13:52:06 |
|                           | Traci Hull (b) (4) |                      |
|                           | (b) (4)            |                      |

**US3402139**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:26:34**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)              | 28 Apr 2021 05:28:07 |
| User signature succeeded. | Frank Eder (b) (4)            | 26 Apr 2021 01:45:47 |
| User entered 'Yes (Y)'    | (b) (4)<br>Traci Hull (b) (4) | 22 Feb 2021 13:52:12 |

**US3402139**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:26:34**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 05:28:07 |
| User entered 'I'  | System           | 22 Feb 2021 13:52:12 |

**US3402139**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:26:34**

[Was this visit performed?](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| User entered 'Yes (Y)'    | (b) (4)            | 22 Feb 2021 13:52:25 |
|                           | Traci Hull (b) (4) |                      |
|                           | (b) (4)            |                      |

**US3402139**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:26:34**

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User               | Time (GMT)           |
|----------------------------|--------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)   | 28 Apr 2021 09:48:32 |
| User signature succeeded.  | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| User entered '22 Feb 2021' | (b) (4)            | 22 Feb 2021 13:52:25 |
|                            | Traci Hull (b) (4) |                      |
|                            | (b) (4)            |                      |

**US3402139**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:26:34**

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User               | Time (GMT)           |
|--------------------------------|--------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)   | 28 Apr 2021 09:48:32 |
| User signature succeeded.      | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| User entered 'Clinic (Clinic)' | Traci Hull (b) (4) | 22 Feb 2021 13:52:25 |

**US3402139**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:26:34**

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 28 Apr 2021 09:48:32 |
| User entered 'VISIT4' | System           | 22 Feb 2021 13:52:25 |



**US3402139**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:26:34**

[Were vital signs assessed?](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)              | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)            | 26 Apr 2021 01:45:47 |
| User entered 'No (N)'     | (b) (4)<br>Tammy Kohn (b) (4) | 31 Mar 2021 17:45:26 |

**US3402139**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:26:34**

**Date of assessment** (*dd MMM yyyy*)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)              | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)            | 26 Apr 2021 01:45:47 |
| User entered empty.       | (b) (4)<br>Tammy Kohn (b) (4) | 31 Mar 2021 17:45:26 |

**US3402139**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:26:34**

**Time of assessment (00:00-23:59)**

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)              | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)            | 26 Apr 2021 01:45:47 |
| User entered empty.       | (b) (4)<br>Tammy Kohn (b) (4) | 31 Mar 2021 17:45:26 |

**US3402139**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:26:34**

[Vital Signs Date and Time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 09:48:32 |
| User entered empty. | System           | 31 Mar 2021 17:45:26 |

US3402139

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:34

Temperature (xxx.x)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)              | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)            | 26 Apr 2021 01:45:47 |
| User entered empty.       | (b) (4)<br>Tammy Kohn (b) (4) | 31 Mar 2021 17:45:26 |
|                           | (b) (4)                       |                      |

US3402139

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:34

[Route of measurement](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)              | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)            | 26 Apr 2021 01:45:47 |
| User entered empty.       | (b) (4)<br>Tammy Kohn (b) (4) | 31 Mar 2021 17:45:26 |

**US3402139**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:26:34**

[If Other, specify](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)              | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)            | 26 Apr 2021 01:45:47 |
| User entered empty.       | (b) (4)<br>Tammy Kohn (b) (4) | 31 Mar 2021 17:45:26 |

**US3402139**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:26:34**

[Pulse \(xxx\)](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)              | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)            | 26 Apr 2021 01:45:47 |
| User entered empty.       | (b) (4)<br>Tammy Kohn (b) (4) | 31 Mar 2021 17:45:26 |



**US3402139**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:26:34**

[Pulse units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 09:48:32 |
| User entered empty. | System           | 31 Mar 2021 17:45:26 |

US3402139

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:34

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)              | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)            | 26 Apr 2021 01:45:47 |
| User entered empty.       | (b) (4)<br>Tammy Kohn (b) (4) | 31 Mar 2021 17:45:26 |

**US3402139**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:26:34**

[Respiratory Rate units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 09:48:32 |
| User entered empty. | System           | 31 Mar 2021 17:45:26 |

**US3402139**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:26:34**

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)              | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)            | 26 Apr 2021 01:45:47 |
| User entered empty.       | (b) (4)<br>Tammy Kohn (b) (4) | 31 Mar 2021 17:45:26 |

**US3402139**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:26:34**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 09:48:32 |
| User entered empty. | System           | 31 Mar 2021 17:45:26 |

**US3402139**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:26:34**

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)              | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)            | 26 Apr 2021 01:45:47 |
| User entered empty.       | (b) (4)<br>Tammy Kohn (b) (4) | 31 Mar 2021 17:45:26 |

**US3402139**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:26:34**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 09:48:32 |
| User entered empty. | System           | 31 Mar 2021 17:45:26 |

US3402139

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:34

Height (derived)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 09:48:32 |



**US3402139**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:26:34**

[Weight \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 09:48:32 |

**US3402139**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:26:34**

[Was the physical examination performed?](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| User entered 'No (N)'     | (b) (4)            | 22 Feb 2021 13:52:40 |
|                           | Traci Hull (b) (4) |                      |
|                           | (b) (4)            |                      |

**US3402139**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:26:34**

**Date of examination (dd MMM yyyy)**

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| User entered empty.       | Traci Hull (b) (4) | 22 Feb 2021 13:52:40 |

**US3402139**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:26:34**

[Was the sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)          | 26 Apr 2021 01:45:47 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 17 Mar 2021 20:21:19 |

**US3402139**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:26:34**

**Collection date** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 09:48:32 |
| User signature succeeded.  | Frank Eder (b) (4)          | 26 Apr 2021 01:45:47 |
| User entered '22 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 17 Mar 2021 20:21:19 |

**US3402139**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:26:34**

[Collection time \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4)          | 26 Apr 2021 01:45:47 |
| User entered '08:31'      | (b) (4)<br>(b) (4), (b) (6) | 17 Mar 2021 20:21:19 |

**US3402139**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:26:34**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 09:48:32 |
| User entered '22 Feb 2021 08:31' | System           | 17 Mar 2021 20:21:19 |

**US3402139**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:26:34**

[Is the participant continuing to the next visit?](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 28 Apr 2021 09:48:32 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| User entered 'Yes (Y)'    | (b) (4)            | 22 Feb 2021 13:52:44 |
|                           | Traci Hull (b) (4) |                      |
|                           | (b) (4)            |                      |



**US3402139**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:26:34**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 09:48:32 |
| User entered 'I'  | System           | 22 Feb 2021 13:52:44 |

**US3402139**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

[Was Contact Attempted?](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 29 Apr 2021 06:59:42 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| User entered 'Yes (Y)'    | Traci Hull (b) (4) | 26 Mar 2021 13:42:25 |

**US3402139**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                      | User               | Time (GMT)           |
|----------------------------|--------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)   | 29 Apr 2021 06:59:42 |
| User signature succeeded.  | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| User entered '26 Mar 2021' | Traci Hull (b) (4) | 26 Mar 2021 13:42:25 |

**US3402139**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

[Please select one status for the follow-up contact](#)

| Audit                                      | User               | Time (GMT)           |
|--|--------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)   | 29 Apr 2021 06:59:42 |
| User signature succeeded.                  | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| User entered 'Contact Made (CONTACT MADE)' | Traci Hull (b) (4) | 26 Mar 2021 13:42:25 |

**US3402139**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:26:34**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 29 Apr 2021 06:59:42 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| User entered empty.       | Traci Hull (b) (4) | 26 Mar 2021 13:42:25 |

**US3402139**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:26:34**

[Is the participant continuing to the next visit?](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 29 Apr 2021 06:59:42 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| User entered 'Yes (Y)'    | Traci Hull (b) (4) | 26 Mar 2021 13:42:28 |

**US3402139**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:26:34**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 06:59:42 |
| User entered 'I'  | System           | 26 Mar 2021 13:42:28 |

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:34

[Was this visit performed?](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 29 Apr 2021 16:33:17 |
|                           |                    |                      |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
|                           | (b) (4)            |                      |
| User entered 'Yes (Y)'    | Traci Hull (b) (4) | 21 Jan 2021 13:15:39 |
|                           | (b) (4)            |                      |



US3402139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:34

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User               | Time (GMT)           |
|----------------------------|--------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)   | 29 Apr 2021 16:33:17 |
|                            |                    |                      |
| User signature succeeded.  | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
|                            | (b) (4)            |                      |
| User entered '21 Jan 2021' | Traci Hull (b) (4) | 21 Jan 2021 13:15:39 |
|                            | (b) (4)            |                      |

US3402139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:34

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User               | Time (GMT)           |
|--------------------------------|--------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)   | 29 Apr 2021 16:33:17 |
|                                |                    |                      |
| User signature succeeded.      | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
|                                | (b) (4)            |                      |
| User entered 'Clinic (Clinic)' | Traci Hull (b) (4) | 21 Jan 2021 13:15:39 |
|                                | (b) (4)            |                      |

**US3402139**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:26:34**

[Folder OID](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 29 Apr 2021 16:33:17 |
|                              |                  |                      |
| User entered 'UNBLND_DECIDE' | System           | 21 Jan 2021 13:15:39 |

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:26:34

Date of updated informed consent (*dd MMM yyyy*)

| Audit                      | User               | Time (GMT)           |
|----------------------------|--------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)   | 29 Apr 2021 16:33:17 |
|                            |                    |                      |
| User signature succeeded.  | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
|                            | (b) (4)            |                      |
| User entered '06 Jan 2021' | Traci Hull (b) (4) | 21 Jan 2021 13:16:18 |
|                            | (b) (4)            |                      |

**US3402139**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:26:34**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

| Audit                                      | User               | Time (GMT)           |
|--|--------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)   | 29 Apr 2021 16:33:17 |
|  |                    |                      |
| User signature succeeded.                  | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
|  | (b) (4)            |                      |
| User entered '0'                           | Traci Hull (b) (4) | 08 Apr 2021 18:23:19 |
|  | (b) (4)            |                      |
| Amendment Manager inserted this DataPoint. | System             | 06 Mar 2021 11:04:51 |

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:26:34

[Was the participant unblinded?](#)

| Audit  | User               | Time (GMT)           |
|--|--------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)   | 29 Apr 2021 16:33:17 |
|  |                    |                      |
| User signature succeeded.  | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
|  | (b) (4)            |                      |
| User closed query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).             | System             | 21 Jan 2021 13:16:34 |
| Query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' answered by data change (Site from System). | System             | 21 Jan 2021 13:16:34 |
| User opened query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).             | System             | 21 Jan 2021 13:16:18 |
| User entered 'Yes (Y)'   | Traci Hull (b) (4) | 21 Jan 2021 13:16:18 |
|  | (b) (4)            |                      |

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:26:34

[Under what version of the Protocol was the Participant unblinded?](#)

| Audit   | User               | Time (GMT)           |
|---|--------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)   | 29 Apr 2021 16:33:17 |
|   |                    |                      |
| User signature succeeded.   | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
|   | (b) (4)            |                      |
| User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field' (Site from DM).             | (b) (4), (b) (6)   | 09 Apr 2021 12:21:22 |
| Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field' answered with 'UPDATED' (Site from DM). | Traci Hull (b) (4) | 08 Apr 2021 18:23:24 |
|   | (b) (4)            |                      |
| User entered 'Amendment 6 or later (Amendment 6 or later)'  | Traci Hull (b) (4) | 08 Apr 2021 18:23:19 |
|   | (b) (4)            |                      |
| User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field' (Site from DM).             | (b) (4), (b) (6)   | 08 Apr 2021 15:31:44 |
| Amendment Manager inserted this DataPoint.  | System             | 06 Mar 2021 11:04:51 |

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:26:34

Date of unblinding (*dd MMM yyyy*)

| Audit   | User               | Time (GMT)           |
|---|--------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)   | 29 Apr 2021 16:33:17 |
|   |                    |                      |
| User signature succeeded.                                     | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
|   | (b) (4)            |                      |
| User entered '21 Jan 2021' reason for change: New Information | Traci Hull (b) (4) | 21 Jan 2021 13:16:34 |
|   | (b) (4)            |                      |
| User entered empty.   | Traci Hull (b) (4) | 21 Jan 2021 13:16:18 |
|   | (b) (4)            |                      |



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:26:34

[Participant randomization assignment](#)

| Audit                                | User               | Time (GMT)           |
|--------------------------------------|--------------------|----------------------|
| Data hard locked.                    | (b) (4), (b) (6)   | 29 Apr 2021 16:33:17 |
|                                      |                    |                      |
| User signature succeeded.            | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
|                                      | (b) (4)            |                      |
| User entered 'mRNA-1273 (mRNA-1273)' | Traci Hull (b) (4) | 21 Jan 2021 13:16:18 |
|                                      | (b) (4)            |                      |

**US3402139**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:26:34**

[Actual Dose 1](#)

| Audit                                | User               | Time (GMT)           |
|--------------------------------------|--------------------|----------------------|
| Data hard locked.                    | (b) (4), (b) (6)   | 29 Apr 2021 16:33:17 |
|                                      |                    |                      |
| User signature succeeded.            | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
|                                      | (b) (4)            |                      |
| User entered 'mRNA-1273 (mRNA-1273)' | Traci Hull (b) (4) | 21 Jan 2021 13:16:18 |
|                                      | (b) (4)            |                      |

US3402139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:26:34

[Actual Dose 2](#)

| Audit                                | User               | Time (GMT)           |
|--------------------------------------|--------------------|----------------------|
| Data hard locked.                    | (b) (4), (b) (6)   | 29 Apr 2021 16:33:17 |
|                                      |                    |                      |
| User signature succeeded.            | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
|                                      | (b) (4)            |                      |
| User entered 'mRNA-1273 (mRNA-1273)' | Traci Hull (b) (4) | 21 Jan 2021 13:16:18 |
|                                      | (b) (4)            |                      |

US3402139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:26:34

[Will participant receive mRNA-1273?](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 29 Apr 2021 16:33:17 |
|                           |                    |                      |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
|                           | (b) (4)            |                      |
| User entered 'No (N)'     | Traci Hull (b) (4) | 21 Jan 2021 13:16:18 |
|                           | (b) (4)            |                      |

**US3402139**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:26:34**

[Placebo Only Flag](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 29 Apr 2021 16:33:17 |
|                     |                  |                      |
| User entered empty. | System           | 21 Jan 2021 13:16:18 |

**US3402139**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:26:34**

[Continuing with mRNA-1273](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 29 Apr 2021 16:33:17 |
|                     |                  |                      |
| User entered empty. | System           | 21 Jan 2021 13:16:18 |

US3402139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:34

[Was the sample collected?](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 29 Apr 2021 16:33:17 |
|                           |                    |                      |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
|                           | (b) (4)            |                      |
| User entered 'Yes (Y)'    | Traci Hull (b) (4) | 21 Jan 2021 13:16:47 |
|                           | (b) (4)            |                      |

US3402139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:34

Collection date (*dd MMM yyyy*)

| Audit                      | User               | Time (GMT)           |
|----------------------------|--------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)   | 29 Apr 2021 16:33:17 |
|                            |                    |                      |
| User signature succeeded.  | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
|                            | (b) (4)            |                      |
| User entered '21 Jan 2021' | Traci Hull (b) (4) | 21 Jan 2021 13:16:47 |
|                            | (b) (4)            |                      |



US3402139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:34

Collection time (00:00-23:59)

| Audit   | User               | Time (GMT)           |
|---|--------------------|----------------------|
| Data hard locked.                                       | (b) (4), (b) (6)   | 29 Apr 2021 16:33:17 |
|   |                    |                      |
| User signature succeeded.                               | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
|   | (b) (4)            |                      |
| User entered '21:33' reason for change: New Information | Traci Hull (b) (4) | 21 Jan 2021 13:17:15 |
|   | (b) (4)            |                      |
| User entered '21:39'                                    | Traci Hull (b) (4) | 21 Jan 2021 13:16:47 |
|   | (b) (4)            |                      |

**US3402139**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:26:34**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 29 Apr 2021 16:33:17 |
|                                  |                  |                      |
| User entered '21 Jan 2021 21:33' | System           | 21 Jan 2021 13:17:15 |
| User entered '21 Jan 2021 21:39' | System           | 21 Jan 2021 13:16:47 |

US3402139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:26:34

[Was the sample collected?](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 29 Apr 2021 16:33:17 |
|                           |                    |                      |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
|                           | (b) (4)            |                      |
| User entered 'Yes (Y)'    | Traci Hull (b) (4) | 21 Jan 2021 13:17:02 |
|                           | (b) (4)            |                      |

**US3402139**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:26:34**

[Collection date \(dd MMM yyyy\)](#)

| Audit                      | User               | Time (GMT)           |
|----------------------------|--------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)   | 29 Apr 2021 16:33:17 |
|                            |                    |                      |
| User signature succeeded.  | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
|                            | (b) (4)            |                      |
| User entered '21 Jan 2021' | Traci Hull (b) (4) | 21 Jan 2021 13:17:02 |
|                            | (b) (4)            |                      |

**US3402139**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:26:34**

[Collection time \(00:00 - 23:59\)](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)   | 29 Apr 2021 16:33:17 |
|                           |                    |                      |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
|                           | (b) (4)            |                      |
| User entered '07:26'      | Traci Hull (b) (4) | 21 Jan 2021 13:17:02 |
|                           | (b) (4)            |                      |

**US3402139**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:26:34**

[Collection Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 29 Apr 2021 16:33:17 |
|                                  |                  |                      |
| User entered '21 Jan 2021 07:26' | System           | 21 Jan 2021 13:17:02 |

**US3402139**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 09 Jun 2021 17:26:34**

[Did the participant experience any adverse events?](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 03 May 2021 06:32:36 |
| User signature succeeded.                                 | Frank Eder (b) (4)          | 14 Mar 2021 14:35:41 |
| DataPoint Verified.                                       | (b) (4)<br>(b) (4), (b) (6) | 20 Nov 2020 18:58:18 |
| User entered 'Yes (Y)' reason for change: New Information | Jennifer Molstead (b) (4)   | 26 Oct 2020 19:21:51 |
| User entered 'No (N)'                                     | Traci Hull (b) (4)          | 03 Sep 2020 19:42:53 |

US3402139

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:34

[AEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.                             | Frank Eder (b) (4)          | 14 Mar 2021 14:35:41 |
| Reviewed for Safety.                                  | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 13:39:55 |
| DataPoint Verified.                                   | (b) (4), (b) (6)            | 20 Nov 2020 19:47:34 |
| User entered<br>'USA-US059-2020-mRNA-1273-P301000014' | System                      | 27 Oct 2020 14:19:05 |
| User entered 'New'                                    | (b) (4), (b) (6)            | 27 Oct 2020 14:19:05 |



US3402139

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:34

[Adverse event](#)

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| User signature succeeded.   | Frank Eder (b) (4)   | 14 Mar 2021 14:35:41 |
| DataPoint Verified.   | (b) (4)              |                      |
|   | (b) (4), (b) (6)     | 21 Jan 2021 16:48:17 |
| User closed query 'Per DM CR: Please review AE and please update to specify the type of Arthritis. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).             | (b) (4), (b) (6)     | 03 Dec 2020 10:22:48 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Knee osteoarthritis - version MedDRA\23.0.  | Coder Import (b) (4) | 02 Dec 2020 08:19:09 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.  | Coder Import (b) (4) | 02 Dec 2020 08:19:09 |
| Data point term sent to Coder   | System               | 01 Dec 2020 14:45:22 |
| Query 'Per DM CR: Please review AE and please update to specify the type of Arthritis. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' answered with 'UPDATED' (Site from DM). | Traci Hull (b) (4)   | 01 Dec 2020 14:44:46 |
| DataPoint Un-verified.  | Traci Hull (b) (4)   | 01 Dec 2020 14:44:31 |
| Coding entries removed.   | (b) (4)              |                      |
|   | Traci Hull (b) (4)   | 01 Dec 2020 14:44:31 |
| User entered 'WORSENING LEFT KNEE OSTEOARTHRITIS' reason for change: Per Query Resolution   | (b) (4)              |                      |
|   | Traci Hull (b) (4)   | 01 Dec 2020 14:44:31 |
| User opened query 'Per DM CR: Please review AE and please update to specify the type of Arthritis. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).             | (b) (4), (b) (6)     | 28 Nov 2020 14:14:19 |
| DataPoint Verified.   | (b) (4), (b) (6)     | 20 Nov 2020 19:47:32 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Knee arthritis - version MedDRA\23.0.   | Coder Import (b) (4) | 10 Nov 2020 11:48:30 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.  | Coder Import (b) (4) | 10 Nov 2020 11:48:30 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:34

[Adverse event](#)

| Audit  | User                      | Time (GMT)           |
|--|---------------------------|----------------------|
| Data point term sent to Coder  | System                    | 07 Nov 2020 13:19:32 |
| Coding entries removed.  | Jennifer Molstead (b) (4) | 07 Nov 2020 13:18:37 |
|  | (b) (4)                   |                      |
| User entered 'WORSENING LEFT KNEE ARTHRITIS' reason for change: Per Query Resolution   | Jennifer Molstead (b) (4) | 07 Nov 2020 13:18:37 |
|  | (b) (4)                   |                      |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Knee arthritis - version MedDRA\\23.0. | Coder Import (b) (4)      | 26 Oct 2020 19:47:07 |
|  | (b) (4)                   |                      |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)      | 26 Oct 2020 19:47:07 |
|  | (b) (4)                   |                      |
| Data point term sent to Coder  | System                    | 26 Oct 2020 19:32:21 |
| User entered 'Left Knee Arthritis'   | Jennifer Molstead (b) (4) | 26 Oct 2020 19:32:02 |
|  | (b) (4)                   |                      |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:34

[Was this a medically-attended AE?](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)                   | 14 Mar 2021 14:35:41 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 20 Nov 2020 19:02:32 |
| User entered 'Yes (Y)'    | Jennifer Molstead (b) (4)<br>(b) (4) | 26 Oct 2020 19:32:02 |

US3402139

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:34

[Was this a Solicited Adverse Reaction?](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)                   | 14 Mar 2021 14:35:41 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 20 Nov 2020 19:47:31 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 26 Oct 2020 19:32:02 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)                   | 14 Mar 2021 14:35:41 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 20 Nov 2020 19:03:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 26 Oct 2020 19:32:02 |

US3402139

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:34

Start date (dd MMM yyyy)

| Audit   | User                                 | Time (GMT)           |
|---|--------------------------------------|----------------------|
| User signature succeeded.   | Frank Eder (b) (4)                   | 14 Mar 2021 14:35:41 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)          | 20 Nov 2020 19:47:28 |
| User closed query 'PV Query: Currently, the start date of the event was reported as the day the subject was hospitalized to undergo a left knee replacement as surgical treatment for the event. Please consider updating the start date of the event to the date the subject first experienced signs and symptoms of the left knee arthritis.' (Site from Safety).             | (b) (4), (b) (6)                     | 09 Nov 2020 21:15:42 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System).   | System                               | 07 Nov 2020 18:24:19 |
| User entered '09 Aug 2020' reason for change: Per Query Resolution  | Tammy Kohn (b) (4)<br>(b) (4)        | 07 Nov 2020 18:24:19 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System).   | System                               | 07 Nov 2020 13:25:20 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System).   | System                               | 07 Nov 2020 13:25:20 |
| User entered 'UN Aug 2020' (non-conformant).  | Jennifer Molstead (b) (4)<br>(b) (4) | 07 Nov 2020 13:25:20 |
| Query 'PV Query: Currently, the start date of the event was reported as the day the subject was hospitalized to undergo a left knee replacement as surgical treatment for the event. Please consider updating the start date of the event to the date the subject first experienced signs and symptoms of the left knee arthritis.' answered with 'UPDATED' (Site from Safety). | Jennifer Molstead (b) (4)<br>(b) (4) | 07 Nov 2020 13:18:51 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System).   | System                               | 07 Nov 2020 13:18:37 |
| User entered 'un Aug 2002' (non-conformant).  | Jennifer Molstead (b) (4)<br>(b) (4) | 07 Nov 2020 13:18:37 |
| User opened query 'PV Query: Currently, the start date of the event was reported as the day the subject was hospitalized to undergo a left knee replacement as surgical treatment for the event. Please consider updating the start date of the event to the date the subject first experienced signs and symptoms of the left knee arthritis.' (Site from Safety).             | (b) (4), (b) (6)                     | 05 Nov 2020 14:51:42 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:34

Start date (*dd MMM yyyy*)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| User entered '12 Oct 2020' | Jennifer Molstead (b) (4)<br>(b) (4) | 26 Oct 2020 19:32:02 |

**US3402139**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:26:34**

[Start time \(00:00-23:59\)](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)                   | 14 Mar 2021 14:35:41 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 20 Nov 2020 19:47:26 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 26 Oct 2020 19:32:02 |



**US3402139**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:26:34**

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Oct 2020 19:32:02 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:34

[Ongoing?](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)                   | 14 Mar 2021 14:35:41 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 20 Nov 2020 19:47:24 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 26 Oct 2020 19:32:02 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:34

If not Ongoing, end date (dd MMM yyyy)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| User signature succeeded.  | Frank Eder (b) (4)                   | 14 Mar 2021 14:35:41 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 20 Nov 2020 19:47:23 |
| User entered '14 Oct 2020' | Jennifer Molstead (b) (4)<br>(b) (4) | 26 Oct 2020 19:32:02 |

**US3402139**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:26:34**

**End time (00:00-23:59)**

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)                   | 14 Mar 2021 14:35:41 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 20 Nov 2020 19:47:21 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 26 Oct 2020 19:32:02 |

**US3402139**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:26:34**

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Oct 2020 19:32:02 |

**US3402139**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:26:34**

[Severity](#)

| Audit  | User                                 | Time (GMT)           |
|--|--------------------------------------|----------------------|
| User signature succeeded.                          | Frank Eder (b) (4)                   | 14 Mar 2021 14:35:41 |
| DataPoint Verified.                                | (b) (4)<br>(b) (4), (b) (6)          | 20 Nov 2020 19:47:18 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Jennifer Molstead (b) (4)<br>(b) (4) | 26 Oct 2020 19:32:02 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:34

[Is the adverse event serious?](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)                   | 14 Mar 2021 14:35:41 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 20 Nov 2020 19:47:11 |
| User entered 'Yes (Y)'    | Jennifer Molstead (b) (4)<br>(b) (4) | 26 Oct 2020 19:32:02 |

US3402139

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:34

[Death](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)                   | 14 Mar 2021 14:35:41 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 20 Nov 2020 19:47:08 |
| User entered '0'          | Jennifer Molstead (b) (4)<br>(b) (4) | 26 Oct 2020 19:32:02 |



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:34

[Life threatening](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)                   | 14 Mar 2021 14:35:41 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 20 Nov 2020 19:47:07 |
| User entered '0'          | Jennifer Molstead (b) (4)<br>(b) (4) | 26 Oct 2020 19:32:02 |

**US3402139**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:26:34**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)                   | 14 Mar 2021 14:35:41 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 20 Nov 2020 19:47:05 |
| User entered 'I'          | Jennifer Molstead (b) (4)<br>(b) (4) | 26 Oct 2020 19:32:02 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:34

Hospital Admission Date (*dd MMM yyyy*)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| User signature succeeded.  | Frank Eder (b) (4)                   | 14 Mar 2021 14:35:41 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 20 Nov 2020 19:02:23 |
| User entered '12 Oct 2020' | Jennifer Molstead (b) (4)<br>(b) (4) | 26 Oct 2020 19:32:02 |

US3402139

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:34

Hospital Discharge Date (*dd MMM yyyy*)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| User signature succeeded.  | Frank Eder (b) (4)                   | 14 Mar 2021 14:35:41 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 20 Nov 2020 19:46:52 |
| User entered '14 Oct 2020' | Jennifer Molstead (b) (4)<br>(b) (4) | 26 Oct 2020 19:32:02 |

**US3402139**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:26:34**

[Admitted to ICU?](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)                   | 14 Mar 2021 14:35:41 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 20 Nov 2020 19:46:56 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 26 Oct 2020 19:32:02 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:34

[Number of Days in ICU](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)                   | 14 Mar 2021 14:35:41 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 20 Nov 2020 19:46:59 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 26 Oct 2020 19:32:02 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:34

[Persistent or significant disability or incapacity](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)                   | 14 Mar 2021 14:35:41 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 20 Nov 2020 19:47:00 |
| User entered '0'          | Jennifer Molstead (b) (4)<br>(b) (4) | 26 Oct 2020 19:32:02 |

US3402139

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:34

[Congenital anomaly or birth defect](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)                   | 14 Mar 2021 14:35:41 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 20 Nov 2020 19:47:01 |
| User entered '0'          | Jennifer Molstead (b) (4)<br>(b) (4) | 26 Oct 2020 19:32:02 |



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:34

[Other medically important event](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)                   | 14 Mar 2021 14:35:41 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 20 Nov 2020 19:47:03 |
| User entered '0'          | Jennifer Molstead (b) (4)<br>(b) (4) | 26 Oct 2020 19:32:02 |

US3402139

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:34

[Relationship to investigational product](#)

| Audit   | User                      | Time (GMT)           |
|---|---------------------------|----------------------|
| User signature succeeded.   | Frank Eder (b) (4)        | 14 Mar 2021 14:35:41 |
| DataPoint Verified.   | (b) (4)                   |                      |
|   | (b) (4), (b) (6)          | 20 Nov 2020 19:46:22 |
|   |                           |                      |
| User closed query 'PV Query: Please provide causality assessment as per protocol guidance. Correct answer should be either Related or Not related.' (Site from Safety).             | (b) (4), (b) (6)          | 09 Nov 2020 21:16:18 |
| Query 'PV Query: Please provide causality assessment as per protocol guidance. Correct answer should be either Related or Not related.' answered with 'UPDATED' (Site from Safety). | Jennifer Molstead (b) (4) | 07 Nov 2020 13:18:58 |
| User entered 'Not Related (NOT RELATED)' reason for change: Per Query Resolution  | (b) (4)                   | 07 Nov 2020 13:18:37 |
| User opened query 'PV Query: Please provide causality assessment as per protocol guidance. Correct answer should be either Related or Not related.' (Site from Safety).             | (b) (4), (b) (6)          | 05 Nov 2020 14:51:21 |
| User entered 'Not Applicable (NOT APPLICABLE)'  | Jennifer Molstead (b) (4) | 26 Oct 2020 19:32:02 |
|   | (b) (4)                   |                      |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:34

[Relationship to Study Procedure](#)

| Audit  | User                                 | Time (GMT)           |
|--|--------------------------------------|----------------------|
| User signature succeeded.  | Frank Eder (b) (4)                   | 14 Mar 2021 14:35:41 |
| User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.<br>' (Site from DM).                 | (b) (4)<br>(b) (4), (b) (6)          | 23 Nov 2020 03:09:14 |
| DataPoint Verified.  | (b) (4), (b) (6)                     | 20 Nov 2020 19:46:24 |
| Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.<br>' answered with 'NOT RELATED' (Site from DM). | Tammy Kohn (b) (4)<br>(b) (4)        | 18 Nov 2020 14:19:36 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error   | Tammy Kohn (b) (4)<br>(b) (4)        | 18 Nov 2020 14:19:29 |
| User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you.<br>' (Site from DM).                 | (b) (4), (b) (6)                     | 18 Nov 2020 09:03:31 |
| User entered 'Not Applicable (NOT APPLICABLE)'   | Jennifer Molstead (b) (4)<br>(b) (4) | 26 Oct 2020 19:32:02 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:34

Action taken with investigational product

| Audit   | User                                 | Time (GMT)           |
|---|--------------------------------------|----------------------|
| User signature succeeded.   | Frank Eder (b) (4)                   | 14 Mar 2021 14:35:41 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)          | 20 Nov 2020 19:46:29 |
| User entered 'None (NONE)' reason for change: Per Query Resolution  | Tammy Kohn (b) (4)<br>(b) (4)        | 17 Nov 2020 21:24:59 |
| User closed query 'PV Query: As the last dose of mRNA-1273 vs placebo was given on 31 Aug 2020, please update the action taken with mRNA-1273 vs placebo from none to not applicable. Please update the EDC accordingly.' (Site from Safety).             | (b) (4), (b) (6)                     | 09 Nov 2020 21:16:05 |
| Query 'PV Query: As the last dose of mRNA-1273 vs placebo was given on 31 Aug 2020, please update the action taken with mRNA-1273 vs placebo from none to not applicable. Please update the EDC accordingly.' answered with 'UPDATED' (Site from Safety). | Jennifer Molstead (b) (4)<br>(b) (4) | 07 Nov 2020 13:19:04 |
| User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution  | Jennifer Molstead (b) (4)<br>(b) (4) | 07 Nov 2020 13:18:37 |
| User opened query 'PV Query: As the last dose of mRNA-1273 vs placebo was given on 31 Aug 2020, please update the action taken with mRNA-1273 vs placebo from none to not applicable. Please update the EDC accordingly.' (Site from Safety).             | (b) (4), (b) (6)                     | 05 Nov 2020 14:49:25 |
| User closed query 'Data is required. Please complete.' (Site from System).  | System                               | 26 Oct 2020 19:32:57 |
| Query 'Data is required. Please complete.' answered by data change (Site from System).  | System                               | 26 Oct 2020 19:32:57 |
| User entered 'None (NONE)' reason for change: Per Query Resolution  | Jennifer Molstead (b) (4)<br>(b) (4) | 26 Oct 2020 19:32:57 |
| User opened query 'Data is required. Please complete.' (Site from System).  | System                               | 26 Oct 2020 19:32:02 |
| User entered empty.   | Jennifer Molstead (b) (4)<br>(b) (4) | 26 Oct 2020 19:32:02 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:34

None

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.   | Frank Eder (b) (4)          | 14 Mar 2021 14:35:41 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 22:06:56 |
| DataPoint Un-verified.  | Tammy Kohn (b) (4)          | 23 Nov 2020 16:02:48 |
| User entered '0' reason for change: Per Query Resolution  | Tammy Kohn (b) (4)          | 23 Nov 2020 16:02:48 |
| DataPoint Verified.   | (b) (4), (b) (6)            | 20 Nov 2020 19:46:34 |
| User closed query 'PV Query: As event start date was updated, please consider updating action taken from not applicable to none. ' (Site from Safety).                  | (b) (4), (b) (6)            | 18 Nov 2020 14:44:53 |
| Query 'PV Query: As event start date was updated, please consider updating action taken from not applicable to none. ' answered with 'data updated' (Site from Safety). | Tammy Kohn (b) (4)          | 17 Nov 2020 21:24:50 |
| User opened query 'PV Query: As event start date was updated, please consider updating action taken from not applicable to none. ' (Site from Safety).                  | (b) (4), (b) (6)            | 17 Nov 2020 21:22:21 |
| User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).                                      | System                      | 26 Oct 2020 19:32:57 |
| User entered '1' reason for change: Per Query Resolution  | Jennifer Molstead (b) (4)   | 26 Oct 2020 19:32:57 |
| User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).                                      | System                      | 26 Oct 2020 19:32:02 |
| User entered '0'  | Jennifer Molstead (b) (4)   | 26 Oct 2020 19:32:02 |

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

| Audit   | User                      | Time (GMT)           |
|---|---------------------------|----------------------|
| User signature succeeded.   | Frank Eder (b) (4)        | 14 Mar 2021 14:35:41 |
|   | (b) (4)                   |                      |
| User closed query 'Please check mark as per source - subject had medications in ConMed Log corresponding with this AE. ' (Site from CRA). DataPoint Verified.                     | (b) (4), (b) (6)          | 24 Nov 2020 20:52:19 |
|   |                           |                      |
|   | (b) (4), (b) (6)          | 23 Nov 2020 22:06:56 |
|   |                           |                      |
| Query 'Please check mark as per source - subject had medications in ConMed Log corresponding with this AE. ' answered with 'data updated' (Site from CRA). DataPoint Un-verified. | Tammy Kohn (b) (4)        | 23 Nov 2020 16:03:17 |
|   | (b) (4)                   |                      |
|   | Tammy Kohn (b) (4)        | 23 Nov 2020 16:02:48 |
|   | (b) (4)                   |                      |
| User entered '1' reason for change: Data Entry Error  | Tammy Kohn (b) (4)        | 23 Nov 2020 16:02:48 |
|   | (b) (4)                   |                      |
| DataPoint Verified.   | (b) (4), (b) (6)          | 20 Nov 2020 19:54:43 |
|   |                           |                      |
| User opened query 'Please check mark as per source - subject had medications in ConMed Log corresponding with this AE. ' (Site from CRA). User entered '0'                        | (b) (4), (b) (6)          | 20 Nov 2020 19:54:12 |
|   |                           |                      |
|   | Jennifer Molstead (b) (4) | 26 Oct 2020 19:32:02 |
|   | (b) (4)                   |                      |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:34

[Concomitant Procedure](#)

| Audit  | User                      | Time (GMT)           |
|--|---------------------------|----------------------|
| User signature succeeded.  | Frank Eder (b) (4)        | 14 Mar 2021 14:35:41 |
|  | (b) (4)                   |                      |
| User closed query 'Please check mark as per source - subject had surgery in Con Procedure Log corresponding with this AE. ' (Site from CRA). DataPoint Verified. | (b) (4), (b) (6)          | 24 Nov 2020 20:52:25 |
|  |                           |                      |
|  | (b) (4), (b) (6)          | 23 Nov 2020 22:06:56 |
|  |                           |                      |
| Query 'Please check mark as per source - subject had surgery in Con Procedure Log corresponding with this AE. ' answered with 'data updated' (Site from CRA).    | Tammy Kohn (b) (4)        | 23 Nov 2020 16:03:24 |
|  | (b) (4)                   |                      |
| DataPoint Un-verified.   | Tammy Kohn (b) (4)        | 23 Nov 2020 16:02:48 |
|  | (b) (4)                   |                      |
| User entered '1' reason for change: Data Entry Error   | Tammy Kohn (b) (4)        | 23 Nov 2020 16:02:48 |
|  | (b) (4)                   |                      |
| DataPoint Verified.  | (b) (4), (b) (6)          | 20 Nov 2020 19:54:41 |
|  |                           |                      |
| User opened query 'Please check mark as per source - subject had surgery in Con Procedure Log corresponding with this AE. ' (Site from CRA).                     | (b) (4), (b) (6)          | 20 Nov 2020 19:54:40 |
|  |                           |                      |
| User entered '0'   | Jennifer Molstead (b) (4) | 26 Oct 2020 19:32:02 |
|  | (b) (4)                   |                      |

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**Form: Adverse Events (1)**

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[Outcome](#)

| Audit   | User                                 | Time (GMT)           |
|---|--------------------------------------|----------------------|
| User signature succeeded.   | Frank Eder (b) (4)                   | 14 Mar 2021 14:35:41 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)          | 20 Nov 2020 19:01:51 |
| User entered 'Recovered/Resolved with Sequelae<br>(RECOVERED/RESOLVED WITH SEQUELAE)' | Jennifer Molstead (b) (4)<br>(b) (4) | 26 Oct 2020 19:32:02 |



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:26:34**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit  | User                                 | Time (GMT)           |
|--|--------------------------------------|----------------------|
| User signature succeeded.                          | Frank Eder (b) (4)                   | 14 Mar 2021 14:35:41 |
| DataPoint Verified.                                | (b) (4)<br>(b) (4), (b) (6)          | 23 Nov 2020 22:06:56 |
| User entered 'Subject undergoing physical therapy' | Jennifer Molstead (b) (4)<br>(b) (4) | 26 Oct 2020 19:32:02 |

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

| Audit  | User                      | Time (GMT)           |
|--|---------------------------|----------------------|
| User signature succeeded.  | Frank Eder (b) (4)        | 14 Mar 2021 14:35:41 |
| DataPoint Verified.  | (b) (4)                   |                      |
|  | (b) (4), (b) (6)          | 21 Jan 2021 16:48:38 |
| User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).  | (b) (4), (b) (6)          | 22 Dec 2020 17:01:03 |
| Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' answered with 'Updated' (Site from Safety).  | Jennifer Molstead (b) (4) | 21 Dec 2020 20:45:27 |
| User closed query 'PV Query: Please confirm the dates of the hemoglobin values, it was reported as 13 Nov 2020 and 14 Nov 2020. Should this be 13 Oct 2020 and 14 Oct 2020. ' (Site from Safety).  | (b) (4), (b) (6)          | 17 Dec 2020 19:09:10 |
| Query 'PV Query: Please confirm the dates of the hemoglobin values, it was reported as 13 Nov 2020 and 14 Nov 2020. Should this be 13 Oct 2020 and 14 Oct 2020. ' answered with 'updated' (Site from Safety).  | Jennifer Molstead (b) (4) | 17 Dec 2020 16:06:40 |
| DataPoint Un-verified.   | Jennifer Molstead (b) (4) | 17 Dec 2020 16:06:27 |
| User entered 'SUBJECT WAS ADMITTED 12OCT2020 FOR A LEFT KNEE REPLACEMENT. SUBJECT WAS DISCHARGED 14OCT2020. SUBJECT DID HAVE COVID 19 TESTING DONE WHICH WAS NEGATIVE. SUBJECT DID HAVE COMPLETE BLOOD COUNT WHICH SHOWED THAT THE HEMAGLOBIN WAS 10.8 ON 13oct2020, AND 11.1 14oct2020 BOTH OF WHICH WERE LOW THE NORMAL RANGE IS 12.0-16.0.' reason for change: Per Query Resolution | Jennifer Molstead (b) (4) | 17 Dec 2020 16:06:27 |
| User opened query 'PV Query: Please confirm the dates of the hemoglobin values, it was reported as 13 Nov 2020 and 14 Nov 2020. Should this be 13 Oct 2020 and 14 Oct 2020. ' (Site from Safety).  | (b) (4), (b) (6)          | 03 Dec 2020 14:14:00 |

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Form: Adverse Events (1)

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[Narrative](#)

| Audit   | User                      | Time (GMT)           |
|---|---------------------------|----------------------|
| User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).   | (b) (4), (b) (6)          | 03 Dec 2020 14:13:50 |
| User closed query 'PV Query: As event resulted in hospitalization, please confirm intensity of grade 2. ' (Site from Safety).   | (b) (4), (b) (6)          | 24 Nov 2020 13:39:46 |
| User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include dates, units and reference ranges if applicable. ' (Site from Safety).  | (b) (4), (b) (6)          | 24 Nov 2020 13:39:45 |
| User closed query 'PV Query: Please provide treatment given for the event including medical intervention. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).             | (b) (4), (b) (6)          | 24 Nov 2020 13:39:43 |
| User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).  | (b) (4), (b) (6)          | 24 Nov 2020 13:39:41 |
| DataPoint Verified.   | (b) (4), (b) (6)          | 23 Nov 2020 22:06:56 |
| Query 'PV Query: Please provide treatment given for the event including medical intervention. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' answered with 'updated' (Site from Safety). | Jennifer Molstead (b) (4) | 23 Nov 2020 18:07:08 |
| Query 'PV Query: As event resulted in hospitalization, please confirm intensity of grade 2. ' answered with 'correct as is' (Site from Safety).   | Jennifer Molstead (b) (4) | 23 Nov 2020 18:06:58 |
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include dates, units and reference ranges if applicable. ' answered with 'updated' (Site from Safety).  | Jennifer Molstead (b) (4) | 23 Nov 2020 18:06:03 |

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

| Audit  | User                      | Time (GMT)           |
|--|---------------------------|----------------------|
| Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' answered with 'updated' (Site from Safety).   | Jennifer Molstead (b) (4) | 23 Nov 2020 18:05:31 |
| User entered 'SUBJECT WAS ADMITTED 12OCT2020 FOR A LEFT KNEE REPLACEMENT. SUBJECT WAS DISCHARGED 14OCT2020. Subject did have covid 19 testing done which was negative. Subject did have complete blood count which showed that the hemoglobin was 10.8 on 13Nov2020, and 11.1 14Nov2020 both of which were low the normal range is 12.0-16.0.' reason for change: Per Query Resolution | Jennifer Molstead (b) (4) | 23 Nov 2020 18:05:19 |
| DataPoint Un-verified.   | (b) (4), (b) (6)          | 20 Nov 2020 19:02:01 |
| DataPoint Verified.  | (b) (4), (b) (6)          | 20 Nov 2020 19:01:59 |
| User opened query 'PV Query: As event resulted in hospitalization, please confirm intensity of grade 2. ' (Site from Safety).  | (b) (4), (b) (6)          | 17 Nov 2020 21:22:59 |
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include dates, units and reference ranges if applicable. ' (Site from Safety).   | (b) (4), (b) (6)          | 17 Nov 2020 21:22:45 |
| User opened query 'PV Query: Please provide treatment given for the event including medical intervention. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).  | (b) (4), (b) (6)          | 17 Nov 2020 21:22:33 |
| User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).   | (b) (4), (b) (6)          | 17 Nov 2020 21:21:49 |
| User closed query 'PV Query: Please confirm left knee arthritis was not considered as medical history.' (Site from Safety).  | (b) (4), (b) (6)          | 09 Nov 2020 21:16:51 |

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:26:34

[Narrative](#)

| Audit   | User                      | Time (GMT)           |
|---|---------------------------|----------------------|
| User closed query 'PV Query: Please provide treatment given for the event including medical intervention. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).  | (b) (4), (b) (6)          | 09 Nov 2020 21:16:43 |
| User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include dates, units and reference ranges if applicable.' (Site from Safety).   | (b) (4), (b) (6)          | 09 Nov 2020 21:16:35 |
| User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).   | (b) (4), (b) (6)          | 09 Nov 2020 21:16:23 |
| Query 'PV Query: Please confirm left knee arthritis was not considered as medical history.' answered with 'This is prior medical history. Will update' (Site from Safety).  | Jennifer Molstead (b) (4) | 07 Nov 2020 13:20:14 |
| Query 'PV Query: Please provide treatment given for the event including medical intervention. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'SUBJECT HAS NOT YET ALLOWED MEDICAL RECORDS TO BE RELEASED' (Site from Safety). | Jennifer Molstead (b) (4) | 07 Nov 2020 13:19:57 |
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include dates, units and reference ranges if applicable.' answered with 'SUBJECT HAS NOT YET ALLOWED MEDICAL RECORDS TO BE RELEASED' (Site from Safety).  | Jennifer Molstead (b) (4) | 07 Nov 2020 13:19:52 |
| Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'UPDATED' (Site from Safety).   | Jennifer Molstead (b) (4) | 07 Nov 2020 13:19:12 |

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Form: Adverse Events (1)

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| Audit  | User                      | Time (GMT)           |
|--|---------------------------|----------------------|
| User entered 'SUBJECT WAS ADMITTED 12OCT2020 FOR A LEFT KNEE REPLACEMENT. SUBJECT WAS DISCHARGED 14OCT2020. AWAITING MEDICAL RECORDS. AT THIS POINT NO MEDICAL RECORDS HAVE BEEN RECEIVED. CAN NOT DETERMIN IF ANY COVID TESTING WAS PERFORMED.' reason for change: Per Query Resolution   | Jennifer Molstead (b) (4) | 07 Nov 2020 13:18:37 |
| User opened query 'PV Query: Please confirm left knee arthritis was not considered as medical history.' (Site from Safety).  | (b) (4), (b) (6)          | 05 Nov 2020 14:51:57 |
| User opened query 'PV Query: Please provide treatment given for the event including medical intervention. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). | (b) (4), (b) (6)          | 05 Nov 2020 14:50:26 |
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include dates, units and reference ranges if applicable.' (Site from Safety).  | (b) (4), (b) (6)          | 05 Nov 2020 14:50:13 |
| User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).  | (b) (4), (b) (6)          | 05 Nov 2020 14:49:44 |
| User entered 'Subject was admitted 12Oct2020 for a left knee replacement. Subject was discharged 14Oct2020. Awaiting medical records.'   | Jennifer Molstead (b) (4) | 26 Oct 2020 19:32:02 |

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:26:34**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 26 Oct 2020 19:32:02 |

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 26 Oct 2020 19:32:02 |



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:26:34**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 26 Oct 2020 19:32:02 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:26:34

Were any prior/concomitant medications and/or vaccinations taken?

| Audit   | User                          | Time (GMT)           |
|---|-------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)              | 03 May 2021 06:32:36 |
| User signature succeeded.   | Frank Eder (b) (4)            | 08 Apr 2021 23:27:02 |
| User closed query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.<br>' (Site from DM).  | (b) (4)<br>(b) (4), (b) (6)   | 18 Feb 2021 12:07:17 |
| Query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.<br>' answered with 'DATA UPDATED TO REFLECT THEPAIN AT INJECTOIN SITE.' (Site from DM). | Tammy Kohn (b) (4)<br>(b) (4) | 17 Feb 2021 17:28:36 |
| User opened query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.<br>' (Site from DM).  | (b) (4), (b) (6)              | 17 Feb 2021 11:18:32 |
| User closed query 'Per source - please verify and add the following to EDC ConMeds. <br /><br />- Hydrocodone/Acetaminophen - 5mg/325mg, PO, PRN for L. Knee Replacement - Start date 12 Oct 2020, ongoing, taken for solicited event - Yes. <br /><br />- Amoxicillin / Clavulanic Acid - 125mg/875mg, PO, QD L. Knee Replacement - Start date 12 Oct 2020, Stop date 22 Oct 2020, taken for solicited event - Yes.' (Site from CRA).                            | (b) (4), (b) (6)              | 24 Nov 2020 20:54:53 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:26:34

Were any prior/concomitant medications and/or vaccinations taken?

| Audit  | User                      | Time (GMT)           |
|--|---------------------------|----------------------|
| Query 'Per source - please verify and add the following to EDC ConMeds. <br /><br />- Hydrocodone/Acetaminophen - 5mg/325mg, PO, PRN for L. Knee Replacement - Start date 12 Oct 2020, ongoing, taken for solicited event - Yes. <br /><br />- Amoxicillin / Clavulanic Acid - 125mg/875mg, PO, QD L. Knee Replacement - Start date 12 Oct 2020, Stop date 22 Oct 2020, taken for solicited event - Yes.' answered with 'updated' (Site from CRA). | Jennifer Molstead (b) (4) | 23 Nov 2020 19:47:58 |
| User opened query 'Per source - please verify and add the following to EDC ConMeds.  | (b) (4), (b) (6)          | 20 Nov 2020 19:45:17 |
| - Hydrocodone/Acetaminophen - 5mg/325mg, PO, PRN for L. Knee Replacement - Start date 12 Oct 2020, ongoing, taken for solicited event - Yes.   |                           |                      |
| - Amoxicillin / Clavulanic Acid - 125mg/875mg, PO, QD L. Knee Replacement - Start date 12 Oct 2020, Stop date 22 Oct 2020, taken for solicited event - Yes.' (Site from CRA).  |                           |                      |
| DataPoint Verified.  | (b) (4), (b) (6)          | 04 Nov 2020 21:18:42 |
| User closed query 'Per ETRTR: Please confirm no medication has been dosed for SAE "Left Knee Arthritis". Update ConMeds and AE CRF otherwise, thanks.' (Site from CRA).  | (b) (4), (b) (6)          | 04 Nov 2020 21:18:40 |
| Query 'Per ETRTR: Please confirm no medication has been dosed for SAE "Left Knee Arthritis". Update ConMeds and AE CRF otherwise, thanks.' answered with 'LEFT KNEE REPLACEMENT IS AN AE ALREADY IN THE SYSTEM. CALLED SPOKE TO PATIENT STATED SHE HAS NOT TAKEN ANYTHING NEW FOR MEDICATIONS. ' (Site from CRA).  | Tammy Kohn (b) (4)        | 30 Oct 2020 14:40:34 |
| User opened query 'Per ETRTR: Please confirm no medication has been dosed for SAE "Left Knee Arthritis". Update ConMeds and AE CRF otherwise, thanks.' (Site from CRA).  | (b) (4), (b) (6)          | 29 Oct 2020 20:51:54 |
| User entered 'Yes (Y)'   | Tarin Gordon (b) (4)      | 01 Aug 2020 16:40:11 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:34

[Name of Medication](#)

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| User signature succeeded.   | Frank Eder (b) (4)   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.   | (b) (4)              |                      |
|   | (b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
|   |                      |                      |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: LEVOCETIRIZINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 03 Aug 2020 11:32:59 |
|   | (b) (4)              |                      |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4) | 03 Aug 2020 11:32:59 |
|   | (b) (4)              |                      |
| Data point term sent to Coder   | System               | 01 Aug 2020 16:51:49 |
| User entered 'LEVOCETIRIZINE'   | Tarin Gordon (b) (4) | 01 Aug 2020 16:50:54 |
|   | (b) (4)              |                      |

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:26:34**

[Prophylaxis](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:50:54 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:34

[Indication](#)

| Audit                                  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User signature succeeded.              | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.                    | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered 'ENVIRONMENTAL ALLERGIES' | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:50:54 |

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:26:34**

[Dose per administration](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
|                           |                      |                      |
| User entered '5'          | Tarin Gordon (b) (4) | 01 Aug 2020 16:50:54 |
|                           | (b) (4)              |                      |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:34

[Dose unit](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered 'mg (mg)'    | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:50:54 |



**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:26:34**

If dose unit is Other, specify

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered empty.       | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:50:54 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:34

[Frequency](#)

| Audit                          | User                 | Time (GMT)           |
|--------------------------------|----------------------|----------------------|
| User signature succeeded.      | Frank Eder (b) (4)   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.            | (b) (4)              |                      |
|                                | (b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
|                                |                      |                      |
| User entered 'once daily (QD)' | Tarin Gordon (b) (4) | 01 Aug 2020 16:50:54 |
|                                | (b) (4)              |                      |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:34

[If frequency is Other, specify](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered empty.       | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:50:54 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:26:34**

[Route of administration](#)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| User signature succeeded.  | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered 'Oral (ORAL)' | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:50:54 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:26:34**

[If route of administration is Other, specify](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered empty.       | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:50:54 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:34

Start date (dd MMM yyyy)

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| User signature succeeded.  | Frank Eder (b) (4)   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)              |                      |
|  | (b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
|  |                      |                      |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4), (b) (6)     | 03 Aug 2020 20:06:02 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'                                 | Tarin Gordon (b) (4) | 01 Aug 2020 16:54:52 |
| answered with 'ONGOING' (Site from System).  | (b) (4)              |                      |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System               | 01 Aug 2020 16:50:54 |
| User entered 'UN May 2019'   | Tarin Gordon (b) (4) | 01 Aug 2020 16:50:54 |
|  | (b) (4)              |                      |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:26:34**

[Start date completely unknown](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered '0'          | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:50:54 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:26:34**

[Ongoing?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered 'Yes (Y)'    | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:50:54 |



**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:26:34**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered empty.       | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:50:54 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:26:34**

[Was this medication taken for solicited event?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:50:54 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:26:34**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 01 Aug 2020 16:50:54 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 01 Aug 2020 16:50:54 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 01 Aug 2020 16:50:54 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:34

[Name of Medication](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| User signature succeeded.   | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: SELECTIVE SEROTONIN (5HT1) AGONISTS, PRODUCT: RIZATRIPTAN BENZOATE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 14 Aug 2020 02:14:46 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4) | 14 Aug 2020 02:14:46 |
| Data point term sent to Coder   | System                          | 01 Aug 2020 16:52:49 |
| User entered 'RIZATRIPTAN BENZOATE'   | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:51:59 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:26:34**

[Prophylaxis](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:51:59 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:34

[Indication](#)

| Audit                             | User                            | Time (GMT)           |
|-----------------------------------|---------------------------------|----------------------|
| User signature succeeded.         | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.               | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered 'MIGRAINE HEADACHES' | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:51:59 |



**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:26:34**

[Dose per administration](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered '10'         | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:51:59 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:26:34**

[Dose unit](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered 'mg (mg)'    | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:51:59 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:26:34**

If dose unit is Other, specify

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
|                           |                      |                      |
| User entered empty.       | Tarin Gordon (b) (4) | 01 Aug 2020 16:51:59 |
|                           | (b) (4)              |                      |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:26:34**

[Frequency](#)

| Audit                          | User                            | Time (GMT)           |
|--------------------------------|---------------------------------|----------------------|
| User signature succeeded.      | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered 'as needed (PRN)' | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:51:59 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:34

If frequency is Other, specify

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered empty.       | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:51:59 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:26:34**

[Route of administration](#)

| Audit                      | User                 | Time (GMT)           |
|----------------------------|----------------------|----------------------|
| User signature succeeded.  | Frank Eder (b) (4)   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)              |                      |
|                            | (b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
|                            |                      |                      |
| User entered 'Oral (ORAL)' | Tarin Gordon (b) (4) | 01 Aug 2020 16:51:59 |
|                            | (b) (4)              |                      |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:34

If route of administration is Other, specify

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered empty.       | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:51:59 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:34

Start date (dd MMM yyyy)

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| User signature succeeded.  | Frank Eder (b) (4)   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)              |                      |
|  | (b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
|  |                      |                      |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4), (b) (6)     | 03 Aug 2020 20:06:07 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'                                 | Tarin Gordon (b) (4) | 01 Aug 2020 16:54:47 |
| answered with 'ONGOING' (Site from System).  | (b) (4)              |                      |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System               | 01 Aug 2020 16:51:59 |
| User entered 'UN UNK 2007'   | Tarin Gordon (b) (4) | 01 Aug 2020 16:51:59 |
|  | (b) (4)              |                      |



**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:26:34**

[Start date completely unknown](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered '0'          | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:51:59 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:26:34**

[Ongoing?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered 'Yes (Y)'    | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:51:59 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:26:34**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered empty.       | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:51:59 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:34

[Was this medication taken for solicited event?](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
|                           |                      |                      |
| User entered 'No (N)'     | Tarin Gordon (b) (4) | 01 Aug 2020 16:51:59 |
|                           | (b) (4)              |                      |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:26:34**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 01 Aug 2020 16:51:59 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 01 Aug 2020 16:51:59 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 01 Aug 2020 16:51:59 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:34

Name of Medication

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User signature succeeded.  | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: CURCUMA LONGA, PRODUCTSYNONYM: TURMERIC [CURCUMA LONGA] - version WHODrug-Global-B3\202003.  | Coder Import (b) (4)<br>(b) (4) | 04 Nov 2020 01:33:35 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.  | Coder Import (b) (4)<br>(b) (4) | 04 Nov 2020 01:33:35 |
| User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: CURCUMA LONGA RHIZOME, PRODUCTSYNONYM: CURCUMIN TURMERIC - version WHODrug-Global-B3\202003. | Coder Import (b) (4)<br>(b) (4) | 30 Sep 2020 14:25:49 |
| 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) | 30 Sep 2020 14:25:49 |
| Data point term sent to Coder  | System                          | 30 Sep 2020 14:24:46 |
| Coding entries removed.  | Traci Hull (b) (4)<br>(b) (4)   | 30 Sep 2020 14:24:37 |
| User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: CURCUMA LONGA RHIZOME, PRODUCTSYNONYM: CURCUMIN TURMERIC - version WHODrug-Global-B3\202003. | Coder Import (b) (4)<br>(b) (4) | 16 Aug 2020 16:05:10 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.  | Coder Import (b) (4)<br>(b) (4) | 16 Aug 2020 16:05:10 |
| Data point term sent to Coder  | System                          | 01 Aug 2020 16:54:51 |
| User entered 'TURMERIC CURCUMIN'   | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:53:56 |



**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:26:34**

[Prophylaxis](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered 'Yes (Y)'    | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:53:56 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:34

[Indication](#)

| Audit                                 | User                 | Time (GMT)           |
|---------------------------------------|----------------------|----------------------|
| User signature succeeded.             | Frank Eder (b) (4)   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.                   | (b) (4)              |                      |
|                                       | (b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
|                                       |                      |                      |
| User entered 'NUTRITIONAL SUPPLEMENT' | Traci Hull (b) (4)   | 30 Sep 2020 14:24:37 |
| reason for change: New Information    | (b) (4)              |                      |
| User entered 'SUPPLEMENT'             | Tarin Gordon (b) (4) | 01 Aug 2020 16:53:56 |
|                                       | (b) (4)              |                      |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:26:34**

[Dose per administration](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered '500'        | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:53:56 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:26:34**

[Dose unit](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered 'mg (mg)'    | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:53:56 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:34

If dose unit is Other, specify

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered empty.       | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:53:56 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:26:34**

[Frequency](#)

| Audit                          | User                 | Time (GMT)           |
|--------------------------------|----------------------|----------------------|
| User signature succeeded.      | Frank Eder (b) (4)   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.            | (b) (4)              |                      |
|                                | (b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
|                                |                      |                      |
| User entered 'as needed (PRN)' | Tarin Gordon (b) (4) | 01 Aug 2020 16:53:56 |
|                                | (b) (4)              |                      |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:34

[If frequency is Other, specify](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered empty.       | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:53:56 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:26:34**

[Route of administration](#)

| Audit                      | User                 | Time (GMT)           |
|----------------------------|----------------------|----------------------|
| User signature succeeded.  | Frank Eder (b) (4)   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)              |                      |
|                            | (b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
|                            |                      |                      |
| User entered 'Oral (ORAL)' | Tarin Gordon (b) (4) | 01 Aug 2020 16:53:56 |
|                            | (b) (4)              |                      |



**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:26:34**

[If route of administration is Other, specify](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered empty.       | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:53:56 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:34

Start date (dd MMM yyyy)

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| User signature succeeded.  | Frank Eder (b) (4)   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)              |                      |
|  | (b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
|  |                      |                      |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4), (b) (6)     | 03 Aug 2020 20:06:11 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'                                 | Tarin Gordon (b) (4) | 01 Aug 2020 16:54:41 |
| answered with 'ONGOING' (Site from System).  | (b) (4)              |                      |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System               | 01 Aug 2020 16:53:56 |
| User entered 'UN Apr 2020'   | Tarin Gordon (b) (4) | 01 Aug 2020 16:53:56 |
|  | (b) (4)              |                      |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:26:34**

[Start date completely unknown](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
|                           |                      |                      |
| User entered '0'          | Tarin Gordon (b) (4) | 01 Aug 2020 16:53:56 |
|                           | (b) (4)              |                      |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:26:34**

[Ongoing?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered 'Yes (Y)'    | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:53:56 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:26:34**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered empty.       | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:53:56 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:26:34**

[Was this medication taken for solicited event?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:53:56 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:26:34**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 01 Aug 2020 16:53:56 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 01 Aug 2020 16:53:56 |



**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 01 Aug 2020 16:53:56 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:34

[Name of Medication](#)

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| User signature succeeded.  | Frank Eder (b) (4)   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)              |                      |
|  | (b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
|  |                      |                      |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM OXIDE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 30 Sep 2020 14:25:50 |
|  | (b) (4)              |                      |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4) | 30 Sep 2020 14:25:50 |
|  | (b) (4)              |                      |
| Data point term sent to Coder  | System               | 30 Sep 2020 14:24:44 |
| Coding entries removed.  | Traci Hull (b) (4)   | 30 Sep 2020 14:24:22 |
|  | (b) (4)              |                      |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM OXIDE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 03 Aug 2020 13:06:59 |
|  | (b) (4)              |                      |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4) | 03 Aug 2020 13:06:59 |
|  | (b) (4)              |                      |
| Data point term sent to Coder  | System               | 01 Aug 2020 16:54:51 |
| User entered 'MAGNESIUM OXIDE'   | Tarin Gordon (b) (4) | 01 Aug 2020 16:54:30 |
|  | (b) (4)              |                      |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:26:34**

[Prophylaxis](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered 'Yes (Y)'    | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:54:30 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:34

[Indication](#)

| Audit                                 | User                 | Time (GMT)           |
|---------------------------------------|----------------------|----------------------|
| User signature succeeded.             | Frank Eder (b) (4)   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.                   | (b) (4)              |                      |
|                                       | (b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
|                                       |                      |                      |
| User entered 'NUTRITIONAL SUPPLEMENT' | Traci Hull (b) (4)   | 30 Sep 2020 14:24:22 |
| reason for change: New Information    | (b) (4)              |                      |
| User entered 'SUPPLEMENT'             | Tarin Gordon (b) (4) | 01 Aug 2020 16:54:30 |
|                                       | (b) (4)              |                      |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:26:34**

[Dose per administration](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
|                           |                      |                      |
| User entered '250'        | Tarin Gordon (b) (4) | 01 Aug 2020 16:54:30 |
|                           | (b) (4)              |                      |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:26:34**

[Dose unit](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered 'mg (mg)'    | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:54:30 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:34

If dose unit is Other, specify

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered empty.       | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:54:30 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:34

[Frequency](#)

| Audit                          | User                 | Time (GMT)           |
|--------------------------------|----------------------|----------------------|
| User signature succeeded.      | Frank Eder (b) (4)   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.            | (b) (4)              |                      |
|                                | (b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
|                                |                      |                      |
| User entered 'as needed (PRN)' | Tarin Gordon (b) (4) | 01 Aug 2020 16:54:30 |
|                                | (b) (4)              |                      |



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:34

[If frequency is Other, specify](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered empty.       | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:54:30 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:26:34**

[Route of administration](#)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| User signature succeeded.  | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered 'Oral (ORAL)' | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:54:30 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:34

If route of administration is Other, specify

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered empty.       | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:54:30 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:34

Start date (dd MMM yyyy)

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| User signature succeeded.  | Frank Eder (b) (4)   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)              |                      |
|  | (b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
|  |                      |                      |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4), (b) (6)     | 03 Aug 2020 20:06:16 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'                                 | Tarin Gordon (b) (4) | 01 Aug 2020 16:54:36 |
| answered with 'ONGOING' (Site from System).  | (b) (4)              |                      |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System               | 01 Aug 2020 16:54:30 |
| User entered 'UN Apr 2020'   | Tarin Gordon (b) (4) | 01 Aug 2020 16:54:30 |
|  | (b) (4)              |                      |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:26:34**

[Start date completely unknown](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered '0'          | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:54:30 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:26:34**

[Ongoing?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered 'Yes (Y)'    | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:54:30 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:26:34**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered empty.       | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:54:30 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:34

[Was this medication taken for solicited event?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Tarin Gordon (b) (4)<br>(b) (4) | 01 Aug 2020 16:54:30 |



**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:26:34**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 01 Aug 2020 16:54:30 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 01 Aug 2020 16:54:30 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 01 Aug 2020 16:54:30 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:34

[Name of Medication](#)

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)     | 01 May 2021 12:41:52 |
| User signature succeeded.  | Frank Eder (b) (4)   | 15 Apr 2021 00:02:45 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 01 Mar 2021 13:34:49 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4) | 01 Mar 2021 13:34:49 |
| Data point term sent to Coder  | System               | 01 Mar 2021 13:34:04 |
| Coding entries removed.  | Tammy Kohn (b) (4)   | 01 Mar 2021 13:33:57 |
| DataPoint Verified.  | (b) (4)              | 24 Nov 2020 17:11:05 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 26 Oct 2020 11:25:44 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4) | 26 Oct 2020 11:25:44 |
| Data point term sent to Coder  | System               | 26 Oct 2020 11:24:41 |
| Coding entries removed.  | Tammy Kohn (b) (4)   | 26 Oct 2020 11:23:49 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 30 Sep 2020 14:25:50 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4) | 30 Sep 2020 14:25:50 |
| Data point term sent to Coder  | System               | 30 Sep 2020 14:24:42 |
| Coding entries removed.  | Traci Hull (b) (4)   | 30 Sep 2020 14:24:03 |

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:34

[Name of Medication](#)

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 08 Sep 2020 15:10:46 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4) | 08 Sep 2020 15:10:46 |
| Data point term sent to Coder  | System               | 08 Sep 2020 15:09:53 |
| User entered 'ACETAMINOPHEN'   | Tarin Gordon (b) (4) | 08 Sep 2020 15:09:44 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:34

[Prophylaxis](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                | 01 May 2021 12:41:52 |
| DataPoint Verified.  | (b) (4), (b) (6)                | 16 Apr 2021 16:45:00 |
| User signature succeeded.  | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| User closed query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is a diary symptom that matches with this medication. If yes, please update 'Prophylaxis' as appropriate.' (Site from DM).             | (b) (4)<br>(b) (4), (b) (6)     | 16 Mar 2021 08:02:59 |
| Query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is a diary symptom that matches with this medication. If yes, please update 'Prophylaxis' as appropriate.' answered with 'UPDATED' (Site from DM). | Tammy Kohn (b) (4)<br>(b) (4)   | 15 Mar 2021 13:07:03 |
| DataPoint Un-verified.   | Tammy Kohn (b) (4)<br>(b) (4)   | 15 Mar 2021 13:06:54 |
| User entered 'No (N)' reason for change: Data Entry Error  | Tammy Kohn (b) (4)<br>(b) (4)   | 15 Mar 2021 13:06:54 |
| User opened query 'Per DM CLR: Prophylaxis = Yes. Please review if this indication should be changed to No as there is a diary symptom that matches with this medication. If yes, please update 'Prophylaxis' as appropriate.' (Site from DM).             | (b) (4), (b) (6)                | 14 Mar 2021 13:38:53 |
| DataPoint Verified.  | (b) (4), (b) (6)                | 24 Nov 2020 17:11:05 |
| User entered 'Yes (Y)'   | Tarin Gordon (b) (4)<br>(b) (4) | 08 Sep 2020 15:09:44 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:34

[Indication](#)

| Audit  | User                                   | Time (GMT)                                   |
|--|--|--|
| Data hard locked.  | (b) (4), (b) (6)                       | 01 May 2021 12:41:52                         |
| DataPoint Verified.  | (b) (4), (b) (6)                       | 16 Apr 2021 16:45:03                         |
| User closed query 'Per CDM re-query: Response noted; Per previous query, please enter in query response that "MILD PAIN AT INJECTION SITE AND BODY ACHES DID NOT MEET AE REPORTING CRITERIA" if AE criteria didn't meet. Else add AE. Thank you ' (Site from DM).<br>User signature succeeded.   | (b) (4), (b) (6)<br>Frank Eder (b) (4) | 15 Apr 2021 04:16:29<br>15 Apr 2021 00:02:45 |
| Query 'Per CDM re-query: Response noted; Per previous query, please enter in query response that "MILD PAIN AT INJECTION SITE AND BODY ACHES DID NOT MEET AE REPORTING CRITERIA" if AE criteria didn't meet. Else add AE. Thank you ' answered with 'NO AE OR SAE AS THIS IS WITHIN THE 7 DAYS OF INJECTION' (Site from DM).   | Tammy Kohn (b) (4)<br>(b) (4)          | 13 Apr 2021 14:32:33                         |
| User closed query 'Per DM CLR-RQ: Response noted. However, please re-review if AE reporting criteria per protocol 8.3.4 has been met. If yes, update to record indication as adverse event. If no, confirm/enter in query response that "MILD PAIN AT INJECTION SITE AND BODY ACHES DID NOT MEET AE REPORTING CRITERIA." Update as appropriate. Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6)                       | 13 Apr 2021 12:05:00                         |
| User opened query 'Per CDM re-query: Response noted; Per previous query, please enter in query response that "MILD PAIN AT INJECTION SITE AND BODY ACHES DID NOT MEET AE REPORTING CRITERIA" if AE criteria didn't meet. Else add AE. Thank you ' (Site from DM).  | (b) (4), (b) (6)                       | 13 Apr 2021 12:04:58                         |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:34

[Indication](#)

| Audit  | User                          | Time (GMT)           |
|--|-------------------------------|----------------------|
| Query 'Per DM CLR-RQ: Response noted. However, please re-review if AE reporting criteria per protocol 8.3.4 has been met. If yes, update to record indication as adverse event. If no, confirm/enter in query response that "MILD PAIN AT INJECTION SITE AND BODY ACHES DID NOT MEET AE REPORTING CRITERIA." Update as appropriate. Otherwise, clarify.' answered with 'WITHIN THE 7 DAY PROTOCOL THEREFORE NO AE REQUIRED' (Site from DM).  | Traci Hull (b) (4)<br>(b) (4) | 09 Apr 2021 17:35:47 |
| User opened query 'Per DM CLR-RQ: Response noted. However, please re-review if AE reporting criteria per protocol 8.3.4 has been met. If yes, update to record indication as adverse event. If no, confirm/enter in query response that "MILD PAIN AT INJECTION SITE AND BODY ACHES DID NOT MEET AE REPORTING CRITERIA." Update as appropriate. Otherwise, clarify.' (Site from DM).   | (b) (4), (b) (6)              | 01 Apr 2021 12:46:36 |
| User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the MILD PAIN AT INJECTION SITE ON DAY 2 OF DIARY AND BODY ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of MILD PAIN AT INJECTION SITE ON DAY 2 OF DIARY AND BODY ACHES did not meet the AE reporting criteria.<br>' (Site from DM). | (b) (4), (b) (6)              | 01 Mar 2021 17:00:29 |



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:34

[Indication](#)

| Audit  | User   | Time (GMT)           |
|--|--|----------------------|
| Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the MILD PAIN AT INJECTION SITE ON DAY 2 OF DIARY AND BODY ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of MILD PAIN AT INJECTION SITE ON DAY 2 OF DIARY AND BODY ACHES did not meet the AE reporting criteria.<br />' answered with 'NO AE OR SAE AS THIS IS WITHIN THE 7 DAYS OF INJECTION' (Site from DM).<br>DataPoint Un-verified. | Tammy Kohn (b) (4)<br>(b) (4)                            | 01 Mar 2021 13:34:39 |
|  | Tammy Kohn (b) (4)<br>(b) (4)                            | 01 Mar 2021 13:33:57 |
| User entered 'MILD PAIN AT INJECTION SITE AND BODY ACHES' reason for change: New Information   | Tammy Kohn (b) (4)<br>(b) (4)                            | 01 Mar 2021 13:33:57 |
| User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the MILD PAIN AT INJECTION SITE ON DAY 2 OF DIARY AND BODY ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of MILD PAIN AT INJECTION SITE ON DAY 2 OF DIARY AND BODY ACHES did not meet the AE reporting criteria.<br>' (Site from DM).<br>DataPoint Verified.   | (b) (4), (b) (6)<br>(b) (4), (b) (6)<br>(b) (4), (b) (6) | 28 Feb 2021 13:43:35 |
|  | (b) (4), (b) (6)<br>(b) (4), (b) (6)<br>(b) (4), (b) (6) | 24 Nov 2020 17:11:05 |

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:34

[Indication](#)

| Audit  | User                          | Time (GMT)           |
|--|-------------------------------|----------------------|
| User closed query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' (Site from DM).   | (b) (4), (b) (6)              | 27 Oct 2020 12:34:03 |
| Query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' answered with 'PATIENT HAD MILD PAIN AT INJECTION SITE NO AE OR SAE ' (Site from DM).   | Tammy Kohn (b) (4)<br>(b) (4) | 26 Oct 2020 11:24:10 |
| User entered 'MILD PAIN AT INJECTION SITE ON DAY 2 OF DIARY AND BODY ACHES' reason for change: New Information   | Tammy Kohn (b) (4)<br>(b) (4) | 26 Oct 2020 11:23:49 |
| User opened query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' (Site from DM).   | (b) (4), (b) (6)              | 26 Oct 2020 09:59:14 |
| Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN ON DAY 2 OF DIARY is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN ON DAY 2 OF DIARY did not meet the AE reporting criteria.' canceled (Site from DM). | (b) (4), (b) (6)              | 05 Oct 2020 11:12:27 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

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[Indication](#)

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| User opened query '<br />Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN ON DAY 2 OF DIARY is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN ON DAY 2 OF DIARY did not meet the AE reporting criteria.' (Site from DM). | (b) (4), (b) (6)     | 02 Oct 2020 04:36:14 |
| User entered 'PAIN ON DAY 2 OF DIARY AND BODY ACHES' reason for change: New Information   | Traci Hull (b) (4)   | 30 Sep 2020 14:24:03 |
| User entered 'PAIN ON DAY 2 OF DIARY'   | Tarin Gordon (b) (4) | 08 Sep 2020 15:09:44 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:34

[Dose per administration](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 01 May 2021 12:41:52 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered '1000'       | Tarin Gordon (b) (4)<br>(b) (4) | 08 Sep 2020 15:09:44 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:34

[Dose unit](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 01 May 2021 12:41:52 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered 'mg (mg)'    | Tarin Gordon (b) (4)<br>(b) (4) | 08 Sep 2020 15:09:44 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:34

If dose unit is Other, specify

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 01 May 2021 12:41:52 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered empty.       | Tarin Gordon (b) (4)<br>(b) (4) | 08 Sep 2020 15:09:44 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:34

[Frequency](#)

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)     | 01 May 2021 12:41:52 |
| DataPoint Verified.   | (b) (4), (b) (6)     | 16 Apr 2021 16:45:31 |
| User signature succeeded.   | Frank Eder (b) (4)   | 15 Apr 2021 00:02:45 |
| User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).             | (b) (4)              |                      |
| Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System). | System               | 17 Feb 2021 17:27:48 |
| DataPoint Un-verified.  | System               | 17 Feb 2021 17:27:48 |
| User entered 'as needed (PRN)' reason for change: Data Entry Error  | Tammy Kohn (b) (4)   | 17 Feb 2021 17:27:48 |
| User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).             | Tammy Kohn (b) (4)   | 17 Feb 2021 17:27:38 |
| DataPoint Verified.   | System               | 17 Feb 2021 17:27:38 |
|   | (b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered 'once (ONCE)'  | (b) (4)              |                      |
|   | Tarin Gordon (b) (4) | 08 Sep 2020 15:09:44 |
|   | (b) (4)              |                      |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

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[If frequency is Other, specify](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 01 May 2021 12:41:52 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered empty.       | Tarin Gordon (b) (4)<br>(b) (4) | 08 Sep 2020 15:09:44 |



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

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[Route of administration](#)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                | 01 May 2021 12:41:52 |
| User signature succeeded.  | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered 'Oral (ORAL)' | Tarin Gordon (b) (4)<br>(b) (4) | 08 Sep 2020 15:09:44 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:34

If route of administration is Other, specify

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 01 May 2021 12:41:52 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered empty.       | Tarin Gordon (b) (4)<br>(b) (4) | 08 Sep 2020 15:09:44 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:34

Start date (dd MMM yyyy)

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)     | 01 May 2021 12:41:52 |
| DataPoint Verified.   | (b) (4), (b) (6)     | 16 Apr 2021 16:45:44 |
| User signature succeeded.                                     | Frank Eder (b) (4)   | 15 Apr 2021 00:02:45 |
| DataPoint Un-verified.  | (b) (4)              |                      |
|   | Tammy Kohn (b) (4)   | 17 Feb 2021 17:27:38 |
| User entered '01 Sep 2020' reason for change: New Information | (b) (4)              | 17 Feb 2021 17:27:38 |
| DataPoint Verified.   | (b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
|   |                      |                      |
| User entered '02 Sep 2020' reason for change: New Information | Traci Hull (b) (4)   | 11 Nov 2020 12:34:02 |
|   | (b) (4)              |                      |
| User entered '2 Sep 2020'                                     | Tarin Gordon (b) (4) | 08 Sep 2020 15:09:44 |
|   | (b) (4)              |                      |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:34

[Start date completely unknown](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 01 May 2021 12:41:52 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered '0'          | Tarin Gordon (b) (4)<br>(b) (4) | 08 Sep 2020 15:09:44 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:34

[Ongoing?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 01 May 2021 12:41:52 |
| User signature succeeded. | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Tarin Gordon (b) (4)<br>(b) (4) | 08 Sep 2020 15:09:44 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:34

If not Ongoing, End date (*dd MMM yyyy*)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 01 May 2021 12:41:52 |
| User signature succeeded.                                     | Frank Eder (b) (4)          | 15 Apr 2021 00:02:45 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 17:11:05 |
| User entered '02 Sep 2020' reason for change: New Information | Traci Hull (b) (4)          | 11 Nov 2020 12:34:02 |
| User entered '2 Sep 2020'                                     | Tarin Gordon (b) (4)        | 08 Sep 2020 15:09:44 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:34

[Was this medication taken for solicited event?](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                | 01 May 2021 12:41:52 |
| User signature succeeded.  | Frank Eder (b) (4)              | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)     | 24 Nov 2020 17:11:05 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                          | 08 Sep 2020 15:10:54 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                          | 08 Sep 2020 15:10:54 |
| User entered 'Yes (Y)' reason for change: Data Entry Error                             | Tarin Gordon (b) (4)<br>(b) (4) | 08 Sep 2020 15:10:54 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                          | 08 Sep 2020 15:09:44 |
| User entered empty.  | Tarin Gordon (b) (4)<br>(b) (4) | 08 Sep 2020 15:09:44 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:26:34**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 12:41:52 |
| User entered empty. | System           | 08 Sep 2020 15:09:44 |



**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 12:41:52 |
| User entered empty. | System           | 08 Sep 2020 15:09:44 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 12:41:52 |
| User entered empty. | System           | 08 Sep 2020 15:09:44 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:34

[Name of Medication](#)

| Audit  | User                                 | Time (GMT)           |
|--|--------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                     | 01 May 2021 12:42:03 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User coded data point as ATC: NERVOUS<br>SYSTEM, ATC: PSYCHOLEPTICS, ATC:<br>HYPNOTICS AND SEDATIVES, ATC:<br>BENZODIAZEPINE RELATED DRUGS,<br>PRODUCT: ZOLPIDEM TARTRATE,<br>PRODUCTSYNONYM: AMBIEN - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)      | 23 Nov 2020 19:55:17 |
| User coded data point as Term Coded data point by<br>User: Coder System - version<br>WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)      | 23 Nov 2020 19:55:17 |
| Data point term sent to Coder  | System                               | 23 Nov 2020 18:19:27 |
| User entered 'Ambien'  | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:18:35 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:34

[Prophylaxis](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:03 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:18:35 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:34

[Indication](#)

| Audit  | User                                 | Time (GMT)           |
|--|--------------------------------------|----------------------|
| Data hard locked.                            | (b) (4), (b) (6)                     | 01 May 2021 12:42:03 |
| User signature succeeded.                    | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.                          | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'Worsening left knee arthritis' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:18:35 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:34

[Dose per administration](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:03 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '5'          | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:18:35 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:34

[Dose unit](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:03 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'mg (mg)'    | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:18:35 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:34

If dose unit is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:03 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:18:35 |



US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:34

[Frequency](#)

| Audit                          | User                                 | Time (GMT)           |
|--------------------------------|--------------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                     | 01 May 2021 12:42:03 |
| User signature succeeded.      | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'as needed (PRN)' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:18:35 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:34

[If frequency is Other, specify](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:03 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:18:35 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:34

[Route of administration](#)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 12:42:03 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'Oral (ORAL)' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:18:35 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:34

If route of administration is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:03 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:18:35 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:34

Start date (dd MMM yyyy)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 12:42:03 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '12 Oct 2020' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:18:35 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:34

[Start date completely unknown](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:03 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '0'          | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:18:35 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:26:34**

[Ongoing?](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:03 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:18:35 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:34

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 12:42:03 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '14 Oct 2020' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:18:35 |



US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:34

[Was this medication taken for solicited event?](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:03 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:18:35 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:26:34**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 12:42:03 |
| User entered empty. | System           | 23 Nov 2020 18:18:35 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 12:42:03 |
| User entered empty. | System           | 23 Nov 2020 18:18:35 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 12:42:03 |
| User entered empty. | System           | 23 Nov 2020 18:18:35 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:34

Name of Medication

| Audit  | User                                 | Time (GMT)           |
|--|--------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                     | 01 May 2021 12:42:07 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: DIPHENYLMETHANE DERIVATIVES, PRODUCT: HYDROXYZINE HYDROCHLORIDE, PRODUCTSYNONYM: ATARAX [HYDROXYZINE HYDROCHLORIDE] - version WHODrug-Global-B3\202003. | Coder Import (b) (4)<br>(b) (4)      | 24 Nov 2020 15:00:12 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.  | Coder Import (b) (4)<br>(b) (4)      | 24 Nov 2020 15:00:12 |
| Data point term sent to Coder  | System                               | 24 Nov 2020 14:53:07 |
| User closed query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' (Site from System).  | System                               | 24 Nov 2020 14:52:18 |
| Query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' answered with 'UPDATED' (Site from System).  | Traci Hull (b) (4)<br>(b) (4)        | 24 Nov 2020 14:52:18 |
| User entered 'ATARAX - hydroxyzine hydrochloride' reason for change: Per Query Resolution  | Traci Hull (b) (4)<br>(b) (4)        | 24 Nov 2020 14:52:09 |
| User opened query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' (Site from System).  | Coder Import (b) (4)<br>(b) (4)      | 24 Nov 2020 13:58:09 |
| Data point term sent to Coder  | System                               | 23 Nov 2020 18:20:28 |
| User entered 'atarax'  | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:19:52 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:34

[Prophylaxis](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:07 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:19:52 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:34

[Indication](#)

| Audit  | User                                 | Time (GMT)           |
|--|--------------------------------------|----------------------|
| Data hard locked.                            | (b) (4), (b) (6)                     | 01 May 2021 12:42:07 |
| User signature succeeded.                    | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.                          | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'Worsening left knee arthritis' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:19:52 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:34

[Dose per administration](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:07 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '50'         | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:19:52 |



US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:34

[Dose unit](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:07 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'mg (mg)'    | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:19:52 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:34

If dose unit is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:07 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:19:52 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:34

[Frequency](#)

| Audit                        | User                                 | Time (GMT)           |
|------------------------------|--------------------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)                     | 01 May 2021 12:42:07 |
| User signature succeeded.    | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.          | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'other (OTHER)' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:19:52 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:34

[If frequency is Other, specify](#)

| Audit                                     | User                                 | Time (GMT)           |
|---|--------------------------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6)                     | 01 May 2021 12:42:07 |
| User signature succeeded.                 | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.                       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'every three hour as needed' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:19:52 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:34

[Route of administration](#)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 12:42:07 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'Oral (ORAL)' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:19:52 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:34

If route of administration is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:07 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:19:52 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:34

Start date (dd MMM yyyy)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 12:42:07 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '12 Oct 2020' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:19:52 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:34

[Start date completely unknown](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:07 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '0'          | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:19:52 |



US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:34

[Ongoing?](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:07 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:19:52 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:34

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 12:42:07 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '14 Oct 2020' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:19:52 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:34

[Was this medication taken for solicited event?](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:07 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:19:52 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:26:34**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 12:42:07 |
| User entered empty. | System           | 23 Nov 2020 18:19:52 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 12:42:07 |
| User entered empty. | System           | 23 Nov 2020 18:19:52 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 12:42:07 |
| User entered empty. | System           | 23 Nov 2020 18:19:52 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:34

[Name of Medication](#)

| Audit  | User                                 | Time (GMT)           |
|--|--------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                     | 01 May 2021 12:42:13 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User coded data point as ATC:<br>MUSCULO-SKELETAL SYSTEM, ATC:<br>ANTIINFLAMMATORY AND ANTIRHEUMATIC<br>PRODUCTS, ATC: ANTIINFLAMMATORY AND<br>ANTIRHEUMATIC PRODUCTS,<br>NON-STEROIDS, ATC: COXIBS, PRODUCT:<br>CELECOXIB, PRODUCTSYNONYM: CELEBREX<br>- version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)      | 24 Nov 2020 06:38:06 |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4)      | 24 Nov 2020 06:38:06 |
| Data point term sent to Coder  | System                               | 23 Nov 2020 18:21:31 |
| User entered 'celebrex'  | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:21:03 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:34

[Prophylaxis](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:13 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:21:03 |



US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:34

[Indication](#)

| Audit  | User                                 | Time (GMT)           |
|--|--------------------------------------|----------------------|
| Data hard locked.                            | (b) (4), (b) (6)                     | 01 May 2021 12:42:13 |
| User signature succeeded.                    | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.                          | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'worsening Left knee arthritis' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:21:03 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:34

[Dose per administration](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:13 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '200'        | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:21:03 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:34

[Dose unit](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:13 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'mg (mg)'    | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:21:03 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:34

If dose unit is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:13 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:21:03 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:34

[Frequency](#)

| Audit                            | User                                 | Time (GMT)           |
|----------------------------------|--------------------------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6)                     | 01 May 2021 12:42:13 |
| User signature succeeded.        | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.              | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'twice daily (BID)' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:21:03 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:34

If frequency is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:13 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:21:03 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:34

[Route of administration](#)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 12:42:13 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'Oral (ORAL)' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:21:03 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:34

If route of administration is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:13 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:21:03 |



US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:34

Start date (dd MMM yyyy)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 12:42:13 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '12 Oct 2020' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:21:03 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:26:34**

[Start date completely unknown](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:13 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '0'          | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:21:03 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:34

[Ongoing?](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:13 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:21:03 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:34

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 12:42:13 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '14 Oct 2020' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:21:03 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:34

[Was this medication taken for solicited event?](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:13 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:21:03 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:26:34**

[Separate Dosage Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:42:13 |
| User entered '2'  | System           | 23 Nov 2020 18:21:03 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Unit Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:42:13 |
| User entered '1'  | System           | 23 Nov 2020 18:21:03 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 01 May 2021 12:42:13 |
| User entered '804 (804)' | System           | 23 Nov 2020 18:21:03 |



US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:34

[Name of Medication](#)

| Audit   | User                                 | Time (GMT)           |
|---|--------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                     | 01 May 2021 12:42:24 |
| User signature succeeded.   | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: BISACODYL, PRODUCTSYNONYM: DULCOLAX [BISACODYL] - version WHODrug-Global-B3\202003. | Coder Import (b) (4)<br>(b) (4)      | 24 Nov 2020 11:55:56 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.   | Coder Import (b) (4)<br>(b) (4)      | 24 Nov 2020 11:55:56 |
| Data point term sent to Coder   | System                               | 23 Nov 2020 18:31:47 |
| User entered 'dulcolax'   | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:31:12 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:34

[Prophylaxis](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:24 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:31:12 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:34

[Indication](#)

| Audit   | User                                 | Time (GMT)           |
|---|--------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                     | 01 May 2021 12:42:24 |
| User signature succeeded.   | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).  | (b) (4)<br>(b) (4), (b) (6)          | 07 Dec 2020 11:59:34 |
| Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' answered with 'TAKING DUE TO TAKING PAIN MEDICATION IN THE HOSPITAL AFTER KNEE SURGERY.' (Site from DM). | Traci Hull (b) (4)<br>(b) (4)        | 04 Dec 2020 21:11:01 |
| User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).  | (b) (4), (b) (6)                     | 04 Dec 2020 06:26:55 |
| DataPoint Verified.   | (b) (4), (b) (6)                     | 24 Nov 2020 17:11:05 |
| User entered 'worsening left knee arthritis'  | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:31:12 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:34

[Dose per administration](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:24 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '10'         | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:31:12 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:34

[Dose unit](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:24 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'mg (mg)'    | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:31:12 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:34

If dose unit is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:24 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:31:12 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:34

[Frequency](#)

| Audit                          | User                                 | Time (GMT)           |
|--------------------------------|--------------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                     | 01 May 2021 12:42:24 |
| User signature succeeded.      | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'as needed (PRN)' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:31:12 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:34

[If frequency is Other, specify](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:24 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:31:12 |



US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:34

[Route of administration](#)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 12:42:24 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'Oral (ORAL)' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:31:12 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:34

If route of administration is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:24 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:31:12 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:34

Start date (dd MMM yyyy)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 12:42:24 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '12 Oct 2020' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:31:12 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:34

[Start date completely unknown](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:24 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '0'          | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:31:12 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:34

[Ongoing?](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:24 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:31:12 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:34

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 12:42:24 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '14 Oct 2020' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:31:12 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:34

[Was this medication taken for solicited event?](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:24 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:31:12 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:26:34**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 12:42:24 |
| User entered empty. | System           | 23 Nov 2020 18:31:12 |



**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 12:42:24 |
| User entered empty. | System           | 23 Nov 2020 18:31:12 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 12:42:24 |
| User entered empty. | System           | 23 Nov 2020 18:31:12 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:34

[Name of Medication](#)

| Audit   | User                                 | Time (GMT)           |
|---|--------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                     | 01 May 2021 12:42:27 |
| User signature succeeded.   | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User coded data point as ATC: NERVOUS<br>SYSTEM, ATC: ANALGESICS, ATC: OTHER<br>ANALGESICS AND ANTIPYRETICS, ATC:<br>SALICYLIC ACID AND DERIVATIVES,<br>PRODUCT: ACETYLSALICYLIC ACID,<br>PRODUCTSYNONYM: ECOTRIN - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)      | 24 Nov 2020 07:11:11 |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)      | 24 Nov 2020 07:11:11 |
| Data point term sent to Coder   | System                               | 23 Nov 2020 18:32:49 |
| User entered 'ecotrin'  | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:31:56 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:34

[Prophylaxis](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:27 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:31:56 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:34

[Indication](#)

| Audit  | User                                 | Time (GMT)           |
|--|--------------------------------------|----------------------|
| Data hard locked.                            | (b) (4), (b) (6)                     | 01 May 2021 12:42:27 |
| User signature succeeded.                    | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.                          | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'worsening left knee arthritis' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:31:56 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:34

[Dose per administration](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:27 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '325'        | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:31:56 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:34

[Dose unit](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:27 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'mg (mg)'    | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:31:56 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:34

If dose unit is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:27 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:31:56 |



US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:34

[Frequency](#)

| Audit                          | User                                 | Time (GMT)           |
|--------------------------------|--------------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                     | 01 May 2021 12:42:27 |
| User signature succeeded.      | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'once daily (QD)' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:31:56 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:34

If frequency is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:27 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:31:56 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:34

[Route of administration](#)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 12:42:27 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'Oral (ORAL)' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:31:56 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:34

If route of administration is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:27 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:31:56 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:34

Start date (dd MMM yyyy)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 12:42:27 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '12 Oct 2020' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:31:56 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:26:34**

[Start date completely unknown](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:27 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '0'          | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:31:56 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:34

[Ongoing?](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:27 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:31:56 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:34

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 12:42:27 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '14 Oct 2020' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:31:56 |



US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:34

[Was this medication taken for solicited event?](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:27 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:31:56 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:26:34**

[Separate Dosage Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:42:27 |
| User entered '1'  | System           | 23 Nov 2020 18:31:56 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Unit Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:42:27 |
| User entered '1'  | System           | 23 Nov 2020 18:31:56 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 01 May 2021 12:42:27 |
| User entered '804 (804)' | System           | 23 Nov 2020 18:31:56 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:34

Name of Medication

| Audit  | User                                 | Time (GMT)           |
|--|--------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                     | 01 May 2021 12:42:37 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)      | 24 Nov 2020 06:34:05 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4)      | 24 Nov 2020 06:34:05 |
| Data point term sent to Coder  | System                               | 23 Nov 2020 18:33:50 |
| User entered 'famotidine'  | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:32:50 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:34

[Prophylaxis](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:37 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:32:50 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:34

[Indication](#)

| Audit   | User                                 | Time (GMT)           |
|---|--------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                     | 01 May 2021 12:42:37 |
| User signature succeeded.   | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).  | (b) (4)<br>(b) (4), (b) (6)          | 07 Dec 2020 12:01:33 |
| Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' answered with 'TAKING DUE TO TAKING PAIN MEDICATION IN THE HOSPITAL AFTER KNEE SURGERY.' (Site from DM). | Traci Hull (b) (4)<br>(b) (4)        | 04 Dec 2020 21:12:03 |
| User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).  | (b) (4), (b) (6)                     | 04 Dec 2020 06:31:51 |
| DataPoint Verified.   | (b) (4), (b) (6)                     | 24 Nov 2020 17:11:05 |
| User entered 'worsening left knee arthritis'  | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:32:50 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:34

[Dose per administration](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:37 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '20'         | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:32:50 |



US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:34

[Dose unit](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:37 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'mg (mg)'    | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:32:50 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:34

If dose unit is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:37 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:32:50 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:34

[Frequency](#)

| Audit                          | User                                 | Time (GMT)           |
|--------------------------------|--------------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                     | 01 May 2021 12:42:37 |
| User signature succeeded.      | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'once daily (QD)' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:32:50 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:34

If frequency is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:37 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:32:50 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:34

[Route of administration](#)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 12:42:37 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'Oral (ORAL)' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:32:50 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:34

If route of administration is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:37 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:32:50 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:34

Start date (dd MMM yyyy)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 12:42:37 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '12 Oct 2020' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:32:50 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:34

[Start date completely unknown](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:37 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '0'          | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:32:50 |



US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:34

[Ongoing?](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:37 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:32:50 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:34

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 12:42:37 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '14 Oct 2020' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:32:50 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:34

[Was this medication taken for solicited event?](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:37 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:32:50 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:26:34**

[Separate Dosage Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:42:37 |
| User entered '1'  | System           | 23 Nov 2020 18:32:50 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Unit Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:42:37 |
| User entered '1'  | System           | 23 Nov 2020 18:32:50 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 01 May 2021 12:42:37 |
| User entered '804 (804)' | System           | 23 Nov 2020 18:32:50 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:34

Name of Medication

| Audit  | User                                 | Time (GMT)           |
|--|--------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                     | 01 May 2021 12:42:43 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)      | 24 Nov 2020 06:34:05 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4)      | 24 Nov 2020 06:34:05 |
| Data point term sent to Coder  | System                               | 23 Nov 2020 18:33:52 |
| User entered 'Famotidine'  | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:33:46 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:34

[Prophylaxis](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:43 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:33:46 |



US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:34

[Indication](#)

| Audit   | User                                 | Time (GMT)           |
|---|--------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                     | 01 May 2021 12:42:43 |
| User signature succeeded.   | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).  | (b) (4)<br>(b) (4), (b) (6)          | 07 Dec 2020 12:02:16 |
| Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' answered with 'TAKING DUE TO TAKING PAIN MEDICATION IN THE HOSPITAL AFTER KNEE SURGERY.' (Site from DM). | Traci Hull (b) (4)<br>(b) (4)        | 04 Dec 2020 21:12:13 |
| User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).  | (b) (4), (b) (6)                     | 04 Dec 2020 06:34:59 |
| DataPoint Verified.   | (b) (4), (b) (6)                     | 24 Nov 2020 17:11:05 |
| User entered 'worsening left knee arthritis'  | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:33:46 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:34

[Dose per administration](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:43 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '20/2'       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:33:46 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:34

[Dose unit](#)

| Audit                        | User                                 | Time (GMT)           |
|------------------------------|--------------------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)                     | 01 May 2021 12:42:43 |
| User signature succeeded.    | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.          | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'Other (OTHER)' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:33:46 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:34

If dose unit is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:43 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'mg/ml'      | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:33:46 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:34

[Frequency](#)

| Audit                          | User                                 | Time (GMT)           |
|--------------------------------|--------------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                     | 01 May 2021 12:42:43 |
| User signature succeeded.      | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'as needed (PRN)' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:33:46 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:34

If frequency is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:43 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:33:46 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:34

[Route of administration](#)

| Audit                                    | User                                 | Time (GMT)           |
|--|--------------------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)                     | 01 May 2021 12:42:43 |
| User signature succeeded.                | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.                      | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'Intravenous (INTRAVENOUS)' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:33:46 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:34

If route of administration is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:43 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:33:46 |



US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:34

Start date (dd MMM yyyy)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 12:42:43 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '12 Oct 2020' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:33:46 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:34

[Start date completely unknown](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:43 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '0'          | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:33:46 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:34

[Ongoing?](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:43 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:33:46 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:34

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 12:42:43 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '14 Oct 2020' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:33:46 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:34

[Was this medication taken for solicited event?](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:43 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:33:46 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:26:34**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 12:42:43 |
| User entered empty. | System           | 23 Nov 2020 18:33:46 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 12:42:43 |
| User entered empty. | System           | 23 Nov 2020 18:33:46 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 12:42:43 |
| User entered empty. | System           | 23 Nov 2020 18:33:46 |



US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:34

[Name of Medication](#)

| Audit  | User                                 | Time (GMT)           |
|--|--------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                     | 01 May 2021 12:42:48 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User coded data point as ATC: NERVOUS<br>SYSTEM, ATC: ANESTHETICS, ATC:<br>ANESTHETICS, GENERAL, ATC: OPIOID<br>ANESTHETICS, PRODUCT: FENTANYL -<br>version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)      | 24 Nov 2020 06:33:47 |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4)      | 24 Nov 2020 06:33:47 |
| Data point term sent to Coder  | System                               | 23 Nov 2020 18:49:19 |
| User entered 'fentanyl'  | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:48:59 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:34

[Prophylaxis](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:48 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:48:59 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:34

[Indication](#)

| Audit  | User                                 | Time (GMT)           |
|--|--------------------------------------|----------------------|
| Data hard locked.                            | (b) (4), (b) (6)                     | 01 May 2021 12:42:48 |
| User signature succeeded.                    | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.                          | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'worsening left knee arthritis' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:48:59 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:34

[Dose per administration](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:48 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '20'         | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:48:59 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:34

[Dose unit](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:48 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'ug (ug)'    | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:48:59 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:34

If dose unit is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:48 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:48:59 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:34

[Frequency](#)

| Audit                          | User                                 | Time (GMT)           |
|--------------------------------|--------------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                     | 01 May 2021 12:42:48 |
| User signature succeeded.      | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'as needed (PRN)' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:48:59 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:34

If frequency is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:48 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:48:59 |



US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:34

[Route of administration](#)

| Audit                                    | User                                 | Time (GMT)           |
|--|--------------------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)                     | 01 May 2021 12:42:48 |
| User signature succeeded.                | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.                      | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'Intravenous (INTRAVENOUS)' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:48:59 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:34

If route of administration is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:48 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:48:59 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:34

Start date (dd MMM yyyy)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 12:42:48 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '12 Oct 2020' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:48:59 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:34

[Start date completely unknown](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:48 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '0'          | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:48:59 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:26:34**

[Ongoing?](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:48 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:48:59 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:26:34**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 12:42:48 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '14 Oct 2020' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:48:59 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:34

[Was this medication taken for solicited event?](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:48 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:48:59 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:26:34**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 12:42:48 |
| User entered empty. | System           | 23 Nov 2020 18:48:59 |



**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 12:42:48 |
| User entered empty. | System           | 23 Nov 2020 18:48:59 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 12:42:48 |
| User entered empty. | System           | 23 Nov 2020 18:48:59 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:26:34

[Name of Medication](#)

| Audit   | User                                 | Time (GMT)           |
|---|--------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                     | 01 May 2021 12:42:55 |
| User signature succeeded.   | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User coded data point as ATC: BLOOD AND<br>BLOOD FORMING ORGANS, ATC:<br>ANTIANEMIC PREPARATIONS, ATC: IRON<br>PREPARATIONS, ATC: IRON BIVALENT, ORAL<br>PREPARATIONS, PRODUCT: FERROUS<br>SULFATE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)      | 24 Nov 2020 07:23:12 |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)      | 24 Nov 2020 07:23:12 |
| Data point term sent to Coder   | System                               | 23 Nov 2020 18:50:20 |
| User entered 'ferrous sulfate'  | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:49:46 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:26:34

[Prophylaxis](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:55 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:49:46 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:26:34

[Indication](#)

| Audit  | User                                 | Time (GMT)           |
|--|--------------------------------------|----------------------|
| Data hard locked.                            | (b) (4), (b) (6)                     | 01 May 2021 12:42:55 |
| User signature succeeded.                    | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.                          | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'worsening left knee arthritis' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:49:46 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:26:34

[Dose per administration](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:55 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '325'        | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:49:46 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:26:34

[Dose unit](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:55 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'mg (mg)'    | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:49:46 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:26:34

If dose unit is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:55 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:49:46 |



US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:26:34

[Frequency](#)

| Audit                          | User                                 | Time (GMT)           |
|--------------------------------|--------------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                     | 01 May 2021 12:42:55 |
| User signature succeeded.      | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'once daily (QD)' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:49:46 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:26:34

[If frequency is Other, specify](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:55 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:49:46 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:26:34

[Route of administration](#)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 12:42:55 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'Oral (ORAL)' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:49:46 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:26:34

If route of administration is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:55 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:49:46 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:26:34

Start date (dd MMM yyyy)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 12:42:55 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '12 Oct 2020' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:49:46 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:26:34

[Start date completely unknown](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:55 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '0'          | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:49:46 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:26:34

[Ongoing?](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:55 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:49:46 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:26:34

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 12:42:55 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '14 Oct 2020' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:49:46 |



US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:26:34

[Was this medication taken for solicited event?](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:55 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:49:46 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:26:34**

[Separate Dosage Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:42:55 |
| User entered '1'  | System           | 23 Nov 2020 18:49:46 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Unit Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:42:55 |
| User entered '1'  | System           | 23 Nov 2020 18:49:46 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 01 May 2021 12:42:55 |
| User entered '804 (804)' | System           | 23 Nov 2020 18:49:46 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:26:34

[Name of Medication](#)

| Audit  | User                                 | Time (GMT)           |
|--|--------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                     | 01 May 2021 12:42:58 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: ENEMAS, PRODUCT: SODIUM PHOSPHATE DIBASIC;SODIUM PHOSPHATE MONOBASIC, PRODUCTSYNONYM: FLEET ENEMA - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)      | 24 Nov 2020 07:25:06 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4)      | 24 Nov 2020 07:25:06 |
| Data point term sent to Coder  | System                               | 23 Nov 2020 18:51:21 |
| User entered 'Fleet Enema'   | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:50:45 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:26:34

[Prophylaxis](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:58 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:50:45 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:26:34

[Indication](#)

| Audit   | User                                 | Time (GMT)           |
|---|--------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                     | 01 May 2021 12:42:58 |
| User signature succeeded.   | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).  | (b) (4)<br>(b) (4), (b) (6)          | 10 Dec 2020 03:16:20 |
| Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' answered with 'TAKING DUE TO TAKING PAIN MEDICATION IN THE HOSPITAL AFTER KNEE SURGERY.' (Site from DM). | Traci Hull (b) (4)<br>(b) (4)        | 04 Dec 2020 21:12:43 |
| User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).  | (b) (4), (b) (6)                     | 04 Dec 2020 06:35:25 |
| DataPoint Verified.   | (b) (4), (b) (6)                     | 24 Nov 2020 17:11:05 |
| User entered 'worsening left knee arthritis'  | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:50:45 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:26:34

[Dose per administration](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:58 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '1'          | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:50:45 |



US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:26:34

[Dose unit](#)

| Audit                        | User                                 | Time (GMT)           |
|------------------------------|--------------------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)                     | 01 May 2021 12:42:58 |
| User signature succeeded.    | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.          | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'Other (OTHER)' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:50:45 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:26:34

If dose unit is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:58 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'bottle'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:50:45 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:26:34

[Frequency](#)

| Audit                          | User                                 | Time (GMT)           |
|--------------------------------|--------------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                     | 01 May 2021 12:42:58 |
| User signature succeeded.      | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'as needed (PRN)' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:50:45 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:26:34

If frequency is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:58 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:50:45 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:26:34

[Route of administration](#)

| Audit                          | User                                 | Time (GMT)           |
|--------------------------------|--------------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                     | 01 May 2021 12:42:58 |
| User signature succeeded.      | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'Rectal (RECTAL)' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:50:45 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:26:34

If route of administration is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:58 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:50:45 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:26:34

Start date (dd MMM yyyy)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 12:42:58 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '12 Oct 2020' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:50:45 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:26:34

[Start date completely unknown](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:58 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '0'          | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:50:45 |



US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:26:34

[Ongoing?](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:58 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:50:45 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:26:34

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 12:42:58 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '14 Oct 2020' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:50:45 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:26:34

[Was this medication taken for solicited event?](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:42:58 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:50:45 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:26:34**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 12:42:58 |
| User entered empty. | System           | 23 Nov 2020 18:50:45 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 12:42:58 |
| User entered empty. | System           | 23 Nov 2020 18:50:45 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 12:42:58 |
| User entered empty. | System           | 23 Nov 2020 18:50:45 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:26:34

Name of Medication

| Audit  | User                                 | Time (GMT)           |
|--|--------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                     | 01 May 2021 12:43:03 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User coded data point as ATC: NERVOUS<br>SYSTEM, ATC: ANALGESICS, ATC: OTHER<br>ANALGESICS AND ANTIPYRETICS, ATC:<br>OTHER ANALGESICS AND ANTIPYRETICS,<br>PRODUCT: GABAPENTIN - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)      | 24 Nov 2020 06:26:11 |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4)      | 24 Nov 2020 06:26:11 |
| Data point term sent to Coder  | System                               | 23 Nov 2020 18:52:22 |
| User entered 'gabapentin'  | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:51:55 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:26:34

[Prophylaxis](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:03 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:51:55 |



US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:26:34

[Indication](#)

| Audit  | User                                 | Time (GMT)           |
|--|--------------------------------------|----------------------|
| Data hard locked.                            | (b) (4), (b) (6)                     | 01 May 2021 12:43:03 |
| User signature succeeded.                    | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.                          | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'worsening left knee arthritis' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:51:55 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:26:34

[Dose per administration](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:03 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '400'        | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:51:55 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:26:34

[Dose unit](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:03 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'mg (mg)'    | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:51:55 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:26:34

If dose unit is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:03 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:51:55 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:26:34

[Frequency](#)

| Audit                            | User                                 | Time (GMT)           |
|----------------------------------|--------------------------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6)                     | 01 May 2021 12:43:03 |
| User signature succeeded.        | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.              | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'twice daily (BID)' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:51:55 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:26:34

If frequency is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:03 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:51:55 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:26:34

[Route of administration](#)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 12:43:03 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'Oral (ORAL)' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:51:55 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:26:34

If route of administration is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:03 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:51:55 |



US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:26:34

Start date (dd MMM yyyy)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 12:43:03 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '12 Oct 2020' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:51:55 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:26:34

[Start date completely unknown](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:03 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '0'          | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:51:55 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:26:34

[Ongoing?](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:03 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:51:55 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:26:34

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 12:43:03 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '14 Oct 2020' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:51:55 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:26:34

[Was this medication taken for solicited event?](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:03 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:51:55 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:26:34**

[Separate Dosage Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:43:03 |
| User entered '2'  | System           | 23 Nov 2020 18:51:55 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Unit Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:43:03 |
| User entered '1'  | System           | 23 Nov 2020 18:51:55 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 01 May 2021 12:43:03 |
| User entered '804 (804)' | System           | 23 Nov 2020 18:51:55 |



US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:26:34

[Name of Medication](#)

| Audit   | User                                 | Time (GMT)           |
|---|--------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                     | 01 May 2021 12:43:08 |
| User signature succeeded.   | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)      | 23 Nov 2020 19:56:14 |
| 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)      | 23 Nov 2020 19:56:14 |
| Data point term sent to Coder   | System                               | 23 Nov 2020 18:53:23 |
| User entered 'Lactated ringers'   | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:53:20 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:26:34

[Prophylaxis](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:08 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:53:20 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:26:34

[Indication](#)

| Audit  | User                                 | Time (GMT)           |
|--|--------------------------------------|----------------------|
| Data hard locked.                            | (b) (4), (b) (6)                     | 01 May 2021 12:43:08 |
| User signature succeeded.                    | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.                          | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'worsening left knee arthritis' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:53:20 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:26:34

[Dose per administration](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:08 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '1000'       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:53:20 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:26:34

[Dose unit](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:08 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'mL (mL)'    | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:53:20 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:26:34

If dose unit is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:08 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:53:20 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:26:34

[Frequency](#)

| Audit                        | User                                 | Time (GMT)           |
|------------------------------|--------------------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)                     | 01 May 2021 12:43:08 |
| User signature succeeded.    | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.          | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'other (OTHER)' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:53:20 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:26:34

If frequency is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:08 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'continuous' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:53:20 |



US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:26:34

[Route of administration](#)

| Audit                                    | User                                 | Time (GMT)           |
|--|--------------------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)                     | 01 May 2021 12:43:08 |
| User signature succeeded.                | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.                      | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'Intravenous (INTRAVENOUS)' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:53:20 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:26:34

If route of administration is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:08 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:53:20 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:26:34

Start date (dd MMM yyyy)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 12:43:08 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '12 Oct 2020' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:53:20 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:26:34

[Start date completely unknown](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:08 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '0'          | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:53:20 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:26:34

[Ongoing?](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:08 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:53:20 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:26:34

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 12:43:08 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '14 Oct 2020' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:53:20 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:26:34

[Was this medication taken for solicited event?](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:08 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:53:20 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:26:34**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 12:43:08 |
| User entered empty. | System           | 23 Nov 2020 18:53:20 |



**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 12:43:08 |
| User entered empty. | System           | 23 Nov 2020 18:53:20 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 12:43:08 |
| User entered empty. | System           | 23 Nov 2020 18:53:20 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:26:34

[Name of Medication](#)

| Audit  | User                                 | Time (GMT)           |
|--|--------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                     | 01 May 2021 12:43:16 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User coded data point as ATC: ANTIINFECTIVES<br>FOR SYSTEMIC USE, ATC: ANTIBACTERIALS<br>FOR SYSTEMIC USE, ATC: QUINOLONE<br>ANTIBACTERIALS, ATC:<br>FLUOROQUINOLONES, PRODUCT:<br>LEVOFLOXACIN, PRODUCTSYNONYM:<br>LOVENOX [LEVOFLOXACIN] - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)      | 24 Nov 2020 08:19:13 |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4)      | 24 Nov 2020 08:19:13 |
| Data point term sent to Coder  | System                               | 23 Nov 2020 18:55:28 |
| User entered 'lovenox'   | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:54:32 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:26:34

[Prophylaxis](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:16 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:54:32 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:26:34

[Indication](#)

| Audit  | User                                 | Time (GMT)           |
|--|--------------------------------------|----------------------|
| Data hard locked.                            | (b) (4), (b) (6)                     | 01 May 2021 12:43:16 |
| User signature succeeded.                    | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.                          | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'worsening left knee arthritis' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:54:32 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:26:34

[Dose per administration](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:16 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '30'         | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:54:32 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:26:34

[Dose unit](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:16 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'mg (mg)'    | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:54:32 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:26:34

If dose unit is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:16 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:54:32 |



US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:26:34

[Frequency](#)

| Audit                          | User                                 | Time (GMT)           |
|--------------------------------|--------------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                     | 01 May 2021 12:43:16 |
| User signature succeeded.      | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'once daily (QD)' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:54:32 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:26:34

[If frequency is Other, specify](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:16 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:54:32 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:26:34

[Route of administration](#)

| Audit                                      | User                                 | Time (GMT)           |
|--|--------------------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                     | 01 May 2021 12:43:16 |
| User signature succeeded.                  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.                        | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'Subcutaneous (SUBCUTANEOUS)' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:54:32 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:26:34

If route of administration is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:16 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:54:32 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:26:34

Start date (dd MMM yyyy)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 12:43:16 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '12 Oct 2020' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:54:32 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:26:34

[Start date completely unknown](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:16 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '0'          | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:54:32 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:26:34

[Ongoing?](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:16 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:54:32 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:26:34

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 12:43:16 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '14 Oct 2020' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:54:32 |



US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:26:34

[Was this medication taken for solicited event?](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:16 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:54:32 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:26:34**

[Separate Dosage Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:43:16 |
| User entered '1'  | System           | 23 Nov 2020 18:54:32 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Unit Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:43:16 |
| User entered '1'  | System           | 23 Nov 2020 18:54:32 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 01 May 2021 12:43:16 |
| User entered '804 (804)' | System           | 23 Nov 2020 18:54:32 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:26:34

Name of Medication

| Audit  | User                                 | Time (GMT)           |
|--|--------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                     | 01 May 2021 12:43:22 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM HYDROXIDE, PRODUCTSYNONYM: MILK OF MAGNESIA - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)      | 24 Nov 2020 08:07:10 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4)      | 24 Nov 2020 08:07:10 |
| Data point term sent to Coder  | System                               | 23 Nov 2020 18:56:29 |
| User entered 'milk of magnesia'  | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:55:39 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:26:34

[Prophylaxis](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:22 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:55:39 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:26:34

[Indication](#)

| Audit  | User                                 | Time (GMT)           |
|--|--------------------------------------|----------------------|
| Data hard locked.                            | (b) (4), (b) (6)                     | 01 May 2021 12:43:22 |
| User signature succeeded.                    | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.                          | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'worsening left knee arthritis' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:55:39 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:26:34

[Dose per administration](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:22 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '30'         | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:55:39 |



US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:26:34

[Dose unit](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:22 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'mL (mL)'    | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:55:39 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:26:34

If dose unit is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:22 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:55:39 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:26:34

[Frequency](#)

| Audit                          | User                                 | Time (GMT)           |
|--------------------------------|--------------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                     | 01 May 2021 12:43:22 |
| User signature succeeded.      | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'as needed (PRN)' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:55:39 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:26:34

If frequency is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:22 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:55:39 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:26:34

[Route of administration](#)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 12:43:22 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'Oral (ORAL)' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:55:39 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:26:34

If route of administration is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:22 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:55:39 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:26:34

Start date (dd MMM yyyy)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 12:43:22 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '12 Oct 2020' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:55:39 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:26:34

[Start date completely unknown](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:22 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '0'          | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:55:39 |



US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:26:34

[Ongoing?](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:22 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:55:39 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:26:34

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 12:43:22 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '14 Oct 2020' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:55:39 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:26:34

[Was this medication taken for solicited event?](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:22 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:55:39 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:26:34**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 12:43:22 |
| User entered empty. | System           | 23 Nov 2020 18:55:39 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 12:43:22 |
| User entered empty. | System           | 23 Nov 2020 18:55:39 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 12:43:22 |
| User entered empty. | System           | 23 Nov 2020 18:55:39 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:26:34

[Name of Medication](#)

| Audit   | User                                 | Time (GMT)           |
|---|--------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                     | 01 May 2021 12:43:27 |
| User signature succeeded.   | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User coded data point as ATC: NERVOUS<br>SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS,<br>ATC: NATURAL OPIUM ALKALOIDS,<br>PRODUCT: MORPHINE - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)      | 24 Nov 2020 07:05:11 |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)      | 24 Nov 2020 07:05:11 |
| Data point term sent to Coder   | System                               | 23 Nov 2020 18:57:33 |
| User entered 'morphine'   | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:56:58 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:26:34

[Prophylaxis](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:27 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:56:58 |



US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:26:34

[Indication](#)

| Audit  | User                                 | Time (GMT)           |
|--|--------------------------------------|----------------------|
| Data hard locked.                            | (b) (4), (b) (6)                     | 01 May 2021 12:43:27 |
| User signature succeeded.                    | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.                          | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'worsening left knee arthritis' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:56:58 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:26:34

[Dose per administration](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:27 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '6'          | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:56:58 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:26:34

[Dose unit](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:27 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'mg (mg)'    | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:56:58 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:26:34

If dose unit is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:27 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:56:58 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:26:34

[Frequency](#)

| Audit                        | User                                 | Time (GMT)           |
|------------------------------|--------------------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)                     | 01 May 2021 12:43:27 |
| User signature succeeded.    | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.          | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'other (OTHER)' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:56:58 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:26:34

[If frequency is Other, specify](#)

| Audit                                  | User                                 | Time (GMT)           |
|--|--------------------------------------|----------------------|
| Data hard locked.                      | (b) (4), (b) (6)                     | 01 May 2021 12:43:27 |
| User signature succeeded.              | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.                    | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'every 3 hours as needed' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:56:58 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:26:34

[Route of administration](#)

| Audit  | User                                 | Time (GMT)           |
|--|--------------------------------------|----------------------|
| Data hard locked.                            | (b) (4), (b) (6)                     | 01 May 2021 12:43:27 |
| User signature succeeded.                    | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.                          | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'Intramuscular (INTRAMUSCULAR)' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:56:58 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:26:34

If route of administration is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:27 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:56:58 |



US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:26:34

Start date (dd MMM yyyy)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 12:43:27 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '12 Oct 2020' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:56:58 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:26:34

[Start date completely unknown](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:27 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '0'          | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:56:58 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:26:34

[Ongoing?](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:27 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:56:58 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:26:34

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 12:43:27 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '14 Oct 2020' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:56:58 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:26:34

[Was this medication taken for solicited event?](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:27 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:56:58 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:26:34**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 12:43:27 |
| User entered empty. | System           | 23 Nov 2020 18:56:58 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 12:43:27 |
| User entered empty. | System           | 23 Nov 2020 18:56:58 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 12:43:27 |
| User entered empty. | System           | 23 Nov 2020 18:56:58 |



US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:26:34

[Name of Medication](#)

| Audit  | User                                 | Time (GMT)           |
|--|--------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                     | 01 May 2021 12:43:31 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User coded data point as ATC: NERVOUS<br>SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS,<br>ATC: NATURAL OPIUM ALKALOIDS,<br>PRODUCT: OXYCODONE - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)      | 24 Nov 2020 04:28:32 |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4)      | 24 Nov 2020 04:28:32 |
| Data point term sent to Coder  | System                               | 23 Nov 2020 18:58:34 |
| User entered 'oxycodone'   | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:57:54 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:26:34

[Prophylaxis](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:31 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:57:54 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:26:34

[Indication](#)

| Audit  | User                                 | Time (GMT)           |
|--|--------------------------------------|----------------------|
| Data hard locked.                            | (b) (4), (b) (6)                     | 01 May 2021 12:43:31 |
| User signature succeeded.                    | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.                          | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'worsening left knee arthritis' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:57:54 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:26:34

[Dose per administration](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:31 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '10'         | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:57:54 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:26:34

[Dose unit](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:31 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'mg (mg)'    | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:57:54 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:26:34

If dose unit is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:31 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:57:54 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:26:34

[Frequency](#)

| Audit                          | User                                 | Time (GMT)           |
|--------------------------------|--------------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                     | 01 May 2021 12:43:31 |
| User signature succeeded.      | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'as needed (PRN)' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:57:54 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:26:34

[If frequency is Other, specify](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:31 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:57:54 |



US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:26:34

[Route of administration](#)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 12:43:31 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'Oral (ORAL)' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:57:54 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:26:34

If route of administration is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:31 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:57:54 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:26:34

Start date (*dd MMM yyyy*)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 12:43:31 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '12 Oct 2020' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:57:54 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:26:34

[Start date completely unknown](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:31 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '0'          | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:57:54 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:26:34

[Ongoing?](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:31 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:57:54 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:26:34

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 12:43:31 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered '14 Oct 2020' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:57:54 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:26:34

[Was this medication taken for solicited event?](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 12:43:31 |
| User signature succeeded. | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'     | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:57:54 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:26:34**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 12:43:31 |
| User entered empty. | System           | 23 Nov 2020 18:57:54 |



**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 12:43:31 |
| User entered empty. | System           | 23 Nov 2020 18:57:54 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 12:43:31 |
| User entered empty. | System           | 23 Nov 2020 18:57:54 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:26:34

[Name of Medication](#)

| Audit  | User                                 | Time (GMT)           |
|--|--------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                     | 01 May 2021 12:43:42 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)          | 23 Nov 2020 22:10:10 |
| User coded data point as ATC: NERVOUS<br>SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS,<br>ATC: OPIOIDS IN COMBINATION WITH<br>NON-OPIOID ANALGESICS, PRODUCT:<br>HYDROCODONE<br>BITARTRATE;PARACETAMOL,<br>PRODUCTSYNONYM:<br>HYDROCODONE/ACETAMINOPHEN - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)      | 23 Nov 2020 20:00:10 |
| User coded data point as Term Coded data point by<br>User: Coder System - version<br>WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)      | 23 Nov 2020 20:00:10 |
| Data point term sent to Coder  | System                               | 23 Nov 2020 19:59:32 |
| User entered<br>'HYDROCODONE/ACETAMINOPHEN' reason for<br>change: Data Entry Error   | Tammy Kohn (b) (4)<br>(b) (4)        | 23 Nov 2020 19:58:52 |
| Data point term sent to Coder  | System                               | 23 Nov 2020 19:57:30 |
| User entered 'HYDROCODONE'   | Tammy Kohn (b) (4)<br>(b) (4)        | 23 Nov 2020 19:57:23 |
| DataPoint activated with code reason code Data<br>required.  | Tammy Kohn (b) (4)<br>(b) (4)        | 23 Nov 2020 19:54:26 |
| DataPoint inactivated with code reason code Data not<br>required.  | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:58:31 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:26:34

[Prophylaxis](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 01 May 2021 12:43:42 |
| User signature succeeded.                                      | Frank Eder (b) (4)          | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 22:10:09 |
| User entered 'No (N)'  | Tammy Kohn (b) (4)          | 23 Nov 2020 19:57:23 |
| DataPoint activated with code reason code Data required.       | Tammy Kohn (b) (4)          | 23 Nov 2020 19:54:26 |
| DataPoint inactivated with code reason code Data not required. | Jennifer Molstead (b) (4)   | 23 Nov 2020 18:58:31 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:26:34

[Indication](#)

| Audit  | User                                 | Time (GMT)           |
|--|--------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                     | 01 May 2021 12:43:42 |
| User signature succeeded.                                      | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)          | 23 Nov 2020 22:10:08 |
| User entered 'LEFT KNEE REPLACEMENT (ARTHROPLASTY)'            | Tammy Kohn (b) (4)                   | 23 Nov 2020 19:57:23 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>Tammy Kohn (b) (4)        | 23 Nov 2020 19:54:26 |
| DataPoint inactivated with code reason code Data not required. | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:58:31 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:26:34

[Dose per administration](#)

| Audit  | User                                 | Time (GMT)           |
|--|--------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                     | 01 May 2021 12:43:42 |
| User signature succeeded.                                      | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)          | 23 Nov 2020 22:10:06 |
| User entered '5/325' reason for change: Data Entry Error       | Tammy Kohn (b) (4)                   | 23 Nov 2020 19:58:52 |
| User entered '5'   | (b) (4)<br>Tammy Kohn (b) (4)        | 23 Nov 2020 19:57:23 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>Tammy Kohn (b) (4)        | 23 Nov 2020 19:54:26 |
| DataPoint inactivated with code reason code Data not required. | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:58:31 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:26:34

[Dose unit](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 01 May 2021 12:43:42 |
| User signature succeeded.                                      | Frank Eder (b) (4)          | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 22:10:05 |
| User entered 'mg (mg)'   | Tammy Kohn (b) (4)          | 23 Nov 2020 19:57:23 |
| DataPoint activated with code reason code Data required.       | Tammy Kohn (b) (4)          | 23 Nov 2020 19:54:26 |
| DataPoint inactivated with code reason code Data not required. | Jennifer Molstead (b) (4)   | 23 Nov 2020 18:58:31 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:26:34

If dose unit is Other, specify

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 01 May 2021 12:43:42 |
| User signature succeeded.                                      | Frank Eder (b) (4)          | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 22:10:03 |
| User entered empty.  | Tammy Kohn (b) (4)          | 23 Nov 2020 19:57:23 |
| DataPoint activated with code reason code Data required.       | Tammy Kohn (b) (4)          | 23 Nov 2020 19:54:26 |
| DataPoint inactivated with code reason code Data not required. | Jennifer Molstead (b) (4)   | 23 Nov 2020 18:58:31 |



US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:26:34

[Frequency](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 01 May 2021 12:43:42 |
| User signature succeeded.                                      | Frank Eder (b) (4)          | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 22:10:02 |
| User entered 'as needed (PRN)'                                 | Tammy Kohn (b) (4)          | 23 Nov 2020 19:57:23 |
| DataPoint activated with code reason code Data required.       | Tammy Kohn (b) (4)          | 23 Nov 2020 19:54:26 |
| DataPoint inactivated with code reason code Data not required. | Jennifer Molstead (b) (4)   | 23 Nov 2020 18:58:31 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:26:34

If frequency is Other, specify

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 01 May 2021 12:43:42 |
| User signature succeeded.                                      | Frank Eder (b) (4)          | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 22:10:01 |
| User entered empty.  | Tammy Kohn (b) (4)          | 23 Nov 2020 19:57:23 |
| DataPoint activated with code reason code Data required.       | Tammy Kohn (b) (4)          | 23 Nov 2020 19:54:26 |
| DataPoint inactivated with code reason code Data not required. | Jennifer Molstead (b) (4)   | 23 Nov 2020 18:58:31 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:26:34

[Route of administration](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 01 May 2021 12:43:42 |
| User signature succeeded.                                      | Frank Eder (b) (4)          | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 22:09:59 |
| User entered 'Oral (ORAL)'                                     | Tammy Kohn (b) (4)          | 23 Nov 2020 19:57:23 |
| DataPoint activated with code reason code Data required.       | Tammy Kohn (b) (4)          | 23 Nov 2020 19:54:26 |
| DataPoint inactivated with code reason code Data not required. | Jennifer Molstead (b) (4)   | 23 Nov 2020 18:58:31 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:26:34

If route of administration is Other, specify

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 01 May 2021 12:43:42 |
| User signature succeeded.                                      | Frank Eder (b) (4)          | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 22:09:58 |
| User entered empty.  | Tammy Kohn (b) (4)          | 23 Nov 2020 19:57:23 |
| DataPoint activated with code reason code Data required.       | Tammy Kohn (b) (4)          | 23 Nov 2020 19:54:26 |
| DataPoint inactivated with code reason code Data not required. | Jennifer Molstead (b) (4)   | 23 Nov 2020 18:58:31 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:26:34

Start date (dd MMM yyyy)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 01 May 2021 12:43:42 |
| User signature succeeded.                                      | Frank Eder (b) (4)          | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 22:09:55 |
| User entered '12 Oct 2020'                                     | Tammy Kohn (b) (4)          | 23 Nov 2020 19:57:23 |
| DataPoint activated with code reason code Data required.       | Tammy Kohn (b) (4)          | 23 Nov 2020 19:54:26 |
| DataPoint inactivated with code reason code Data not required. | Jennifer Molstead (b) (4)   | 23 Nov 2020 18:58:31 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:26:34

[Start date completely unknown](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 01 May 2021 12:43:42 |
| User signature succeeded.                                      | Frank Eder (b) (4)          | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 22:09:56 |
| User entered '0'   | Tammy Kohn (b) (4)          | 23 Nov 2020 19:57:23 |
| DataPoint activated with code reason code Data required.       | Tammy Kohn (b) (4)          | 23 Nov 2020 19:54:26 |
| DataPoint inactivated with code reason code Data not required. | Jennifer Molstead (b) (4)   | 23 Nov 2020 18:58:31 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:26:34

[Ongoing?](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 01 May 2021 12:43:42 |
| User signature succeeded.                                      | Frank Eder (b) (4)          | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 17:11:05 |
| User entered 'No (N)'  | Tammy Kohn (b) (4)          | 23 Nov 2020 19:57:23 |
| DataPoint activated with code reason code Data required.       | Tammy Kohn (b) (4)          | 23 Nov 2020 19:54:26 |
| DataPoint inactivated with code reason code Data not required. | Jennifer Molstead (b) (4)   | 23 Nov 2020 18:58:31 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:26:34

If not Ongoing, End date (dd MMM yyyy)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 01 May 2021 12:43:42 |
| User signature succeeded.                                      | Frank Eder (b) (4)          | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 17:11:05 |
| User entered '22 Oct 2020'                                     | Tammy Kohn (b) (4)          | 23 Nov 2020 19:57:23 |
| DataPoint activated with code reason code Data required.       | Tammy Kohn (b) (4)          | 23 Nov 2020 19:54:26 |
| DataPoint inactivated with code reason code Data not required. | Jennifer Molstead (b) (4)   | 23 Nov 2020 18:58:31 |



US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:26:34

[Was this medication taken for solicited event?](#)

| Audit  | User                                 | Time (GMT)           |
|--|--------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                     | 01 May 2021 12:43:42 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)          | 21 Jan 2021 16:46:33 |
| User closed query 'Per CDM RQ: Response noted. However, the indication of Left Knee Replacement is not a Solicited Event per protocol. Please review and updated. ' (Site from DM).  | (b) (4), (b) (6)                     | 18 Dec 2020 07:55:38 |
| Query 'Per CDM RQ: Response noted. However, the indication of Left Knee Replacement is not a Solicited Event per protocol. Please review and updated. ' answered with 'updated' (Site from DM).  | Jennifer Molstead (b) (4)<br>(b) (4) | 17 Dec 2020 16:12:28 |
| DataPoint Un-verified.   | Jennifer Molstead (b) (4)<br>(b) (4) | 17 Dec 2020 16:12:20 |
| User entered 'No (N)' reason for change: Data Entry Error  | Jennifer Molstead (b) (4)<br>(b) (4) | 17 Dec 2020 16:12:20 |
| User opened query 'Per CDM RQ: Response noted. However, the indication of Left Knee Replacement is not a Solicited Event per protocol. Please review and updated. ' (Site from DM).  | (b) (4), (b) (6)                     | 08 Dec 2020 18:43:55 |
| User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification. ' (Site from DM). | (b) (4), (b) (6)                     | 08 Dec 2020 18:43:55 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:26:34

Was this medication taken for solicited event?

| Audit   | User                                   | Time (GMT)           |
|---|--|----------------------|
| Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification.<br />' answered with 'TAKING BECAUSE OF LEFT KNEE REPLACEMENT' (Site from DM). | Traci Hull (b) (4)<br>(b) (4)          | 04 Dec 2020 21:15:08 |
| User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification.<br>' (Site from DM).   | (b) (4), (b) (6)<br>(b) (4)            | 04 Dec 2020 06:47:33 |
| DataPoint Verified.   | (b) (4), (b) (6)<br>(b) (4)<br>(b) (4) | 23 Nov 2020 22:09:52 |
| User entered 'Yes (Y)'  | Tammy Kohn (b) (4)<br>(b) (4)          | 23 Nov 2020 19:57:23 |
| DataPoint activated with code reason code Data required.  | Tammy Kohn (b) (4)<br>(b) (4)          | 23 Nov 2020 19:54:26 |
| DataPoint inactivated with code reason code Data not required.  | Jennifer Molstead (b) (4)<br>(b) (4)   | 23 Nov 2020 18:58:31 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:26:34

[Separate Dosage Number \(derived\)](#)

| Audit  | User                      | Time (GMT)           |
|--|---------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)          | 01 May 2021 12:43:42 |
| User entered empty.  | System                    | 23 Nov 2020 19:57:23 |
| DataPoint activated with code reason code Data required.       | Tammy Kohn (b) (4)        | 23 Nov 2020 19:54:26 |
| DataPoint inactivated with code reason code Data not required. | Jennifer Molstead (b) (4) | 23 Nov 2020 18:58:31 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:26:34

[Interval Dosage Unit Number \(derived\)](#)

| Audit  | User                      | Time (GMT)           |
|--|---------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)          | 01 May 2021 12:43:42 |
| User entered empty.  | System                    | 23 Nov 2020 19:57:23 |
| DataPoint activated with code reason code Data required.       | Tammy Kohn (b) (4)        | 23 Nov 2020 19:54:26 |
| DataPoint inactivated with code reason code Data not required. | Jennifer Molstead (b) (4) | 23 Nov 2020 18:58:31 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:26:34

[Interval Dosage Definition \(derived\)](#)

| Audit  | User                      | Time (GMT)           |
|--|---------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)          | 01 May 2021 12:43:42 |
| User entered empty.  | System                    | 23 Nov 2020 19:57:23 |
| DataPoint activated with code reason code Data required.       | Tammy Kohn (b) (4)        | 23 Nov 2020 19:54:26 |
| DataPoint inactivated with code reason code Data not required. | Jennifer Molstead (b) (4) | 23 Nov 2020 18:58:31 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:26:34

Name of Medication

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)     | 01 May 2021 12:43:47 |
| User signature succeeded.   | Frank Eder (b) (4)   | 15 Apr 2021 00:02:45 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANIC ACID - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4) | 08 Dec 2020 17:32:52 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4) | 08 Dec 2020 17:32:52 |
| DataPoint Verified.   | (b) (4), (b) (6)     | 23 Nov 2020 22:10:24 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM, PRODUCTSYNONYM: AMOXICILLIN/CLAVULANIC ACID - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 23 Nov 2020 20:03:04 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4) | 23 Nov 2020 20:03:04 |
| Data point term sent to Coder   | System               | 23 Nov 2020 20:01:34 |
| User entered 'AMOXICILLIN/CLAVULANIC ACID'  | Tammy Kohn (b) (4)   | 23 Nov 2020 20:00:55 |
| DataPoint activated with code reason code Data required.  | Tammy Kohn (b) (4)   | 23 Nov 2020 19:59:32 |
| DataPoint inactivated with code reason code Data not required.  | Tammy Kohn (b) (4)   | 23 Nov 2020 19:58:34 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:26:34

[Prophylaxis](#)

| Audit  | User                          | Time (GMT)           |
|--|-------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)              | 01 May 2021 12:43:47 |
| User signature succeeded.                                      | Frank Eder (b) (4)            | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)   | 23 Nov 2020 22:10:25 |
| User entered 'No (N)'  | Tammy Kohn (b) (4)            | 23 Nov 2020 20:00:55 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>Tammy Kohn (b) (4) | 23 Nov 2020 19:59:32 |
| DataPoint inactivated with code reason code Data not required. | (b) (4)<br>Tammy Kohn (b) (4) | 23 Nov 2020 19:58:34 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:26:34

[Indication](#)

| Audit  | User                          | Time (GMT)           |
|--|-------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)              | 01 May 2021 12:43:47 |
| User signature succeeded.                                      | Frank Eder (b) (4)            | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)   | 23 Nov 2020 22:10:26 |
| User entered 'LEFT KNEE REPLACEMENT (ARTHOPLASTY)'             | Tammy Kohn (b) (4)            | 23 Nov 2020 20:00:55 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>Tammy Kohn (b) (4) | 23 Nov 2020 19:59:32 |
| DataPoint inactivated with code reason code Data not required. | (b) (4)<br>Tammy Kohn (b) (4) | 23 Nov 2020 19:58:34 |



US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:26:34

[Dose per administration](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 01 May 2021 12:43:47 |
| User signature succeeded.                                      | Frank Eder (b) (4)          | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 22:10:27 |
| User entered '125/875'   | Tammy Kohn (b) (4)          | 23 Nov 2020 20:00:55 |
| DataPoint activated with code reason code Data required.       | Tammy Kohn (b) (4)          | 23 Nov 2020 19:59:32 |
| DataPoint inactivated with code reason code Data not required. | Tammy Kohn (b) (4)          | 23 Nov 2020 19:58:34 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:26:34

[Dose unit](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 01 May 2021 12:43:47 |
| User signature succeeded.                                      | Frank Eder (b) (4)          | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 22:10:28 |
| User entered 'mg (mg)'   | Tammy Kohn (b) (4)          | 23 Nov 2020 20:00:55 |
| DataPoint activated with code reason code Data required.       | Tammy Kohn (b) (4)          | 23 Nov 2020 19:59:32 |
| DataPoint inactivated with code reason code Data not required. | Tammy Kohn (b) (4)          | 23 Nov 2020 19:58:34 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:26:34

If dose unit is Other, specify

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 01 May 2021 12:43:47 |
| User signature succeeded.                                      | Frank Eder (b) (4)          | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 22:10:30 |
| User entered empty.  | Tammy Kohn (b) (4)          | 23 Nov 2020 20:00:55 |
| DataPoint activated with code reason code Data required.       | Tammy Kohn (b) (4)          | 23 Nov 2020 19:59:32 |
| DataPoint inactivated with code reason code Data not required. | Tammy Kohn (b) (4)          | 23 Nov 2020 19:58:34 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:26:34

[Frequency](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 01 May 2021 12:43:47 |
| User signature succeeded.                                      | Frank Eder (b) (4)          | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 22:10:31 |
| User entered 'once daily (QD)'                                 | Tammy Kohn (b) (4)          | 23 Nov 2020 20:00:55 |
| DataPoint activated with code reason code Data required.       | Tammy Kohn (b) (4)          | 23 Nov 2020 19:59:32 |
| DataPoint inactivated with code reason code Data not required. | Tammy Kohn (b) (4)          | 23 Nov 2020 19:58:34 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:26:34

If frequency is Other, specify

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 01 May 2021 12:43:47 |
| User signature succeeded.                                      | Frank Eder (b) (4)          | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 22:10:33 |
| User entered empty.  | Tammy Kohn (b) (4)          | 23 Nov 2020 20:00:55 |
| DataPoint activated with code reason code Data required.       | Tammy Kohn (b) (4)          | 23 Nov 2020 19:59:32 |
| DataPoint inactivated with code reason code Data not required. | Tammy Kohn (b) (4)          | 23 Nov 2020 19:58:34 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:26:34

[Route of administration](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 01 May 2021 12:43:47 |
| User signature succeeded.                                      | Frank Eder (b) (4)          | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 22:10:35 |
| User entered 'Oral (ORAL)'                                     | Tammy Kohn (b) (4)          | 23 Nov 2020 20:00:55 |
| DataPoint activated with code reason code Data required.       | Tammy Kohn (b) (4)          | 23 Nov 2020 19:59:32 |
| DataPoint inactivated with code reason code Data not required. | Tammy Kohn (b) (4)          | 23 Nov 2020 19:58:34 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:26:34

If route of administration is Other, specify

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 01 May 2021 12:43:47 |
| User signature succeeded.                                      | Frank Eder (b) (4)          | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 22:10:36 |
| User entered empty.  | Tammy Kohn (b) (4)          | 23 Nov 2020 20:00:55 |
| DataPoint activated with code reason code Data required.       | Tammy Kohn (b) (4)          | 23 Nov 2020 19:59:32 |
| DataPoint inactivated with code reason code Data not required. | Tammy Kohn (b) (4)          | 23 Nov 2020 19:58:34 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:26:34

Start date (dd MMM yyyy)

| Audit  | User                          | Time (GMT)           |
|--|-------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)              | 01 May 2021 12:43:47 |
| User signature succeeded.                                      | Frank Eder (b) (4)            | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)   | 23 Nov 2020 22:10:37 |
| User entered '12 Oct 2020'                                     | Tammy Kohn (b) (4)            | 23 Nov 2020 20:00:55 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>Tammy Kohn (b) (4) | 23 Nov 2020 19:59:32 |
| DataPoint inactivated with code reason code Data not required. | (b) (4)<br>Tammy Kohn (b) (4) | 23 Nov 2020 19:58:34 |



US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:26:34

[Start date completely unknown](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 01 May 2021 12:43:47 |
| User signature succeeded.                                      | Frank Eder (b) (4)          | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 22:10:39 |
| User entered '0'   | Tammy Kohn (b) (4)          | 23 Nov 2020 20:00:55 |
| DataPoint activated with code reason code Data required.       | Tammy Kohn (b) (4)          | 23 Nov 2020 19:59:32 |
| DataPoint inactivated with code reason code Data not required. | Tammy Kohn (b) (4)          | 23 Nov 2020 19:58:34 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:26:34

[Ongoing?](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 01 May 2021 12:43:47 |
| User signature succeeded.                                      | Frank Eder (b) (4)          | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 22:10:40 |
| User entered 'No (N)'  | Tammy Kohn (b) (4)          | 23 Nov 2020 20:00:55 |
| DataPoint activated with code reason code Data required.       | Tammy Kohn (b) (4)          | 23 Nov 2020 19:59:32 |
| DataPoint inactivated with code reason code Data not required. | Tammy Kohn (b) (4)          | 23 Nov 2020 19:58:34 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:26:34

If not Ongoing, End date (*dd MMM yyyy*)

| Audit  | User                          | Time (GMT)           |
|--|-------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)              | 01 May 2021 12:43:47 |
| User signature succeeded.                                      | Frank Eder (b) (4)            | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)   | 23 Nov 2020 22:10:41 |
| User entered '22 Oct 2020'                                     | Tammy Kohn (b) (4)            | 23 Nov 2020 20:00:55 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>Tammy Kohn (b) (4) | 23 Nov 2020 19:59:32 |
| DataPoint inactivated with code reason code Data not required. | (b) (4)<br>Tammy Kohn (b) (4) | 23 Nov 2020 19:58:34 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:26:34

[Was this medication taken for solicited event?](#)

| Audit  | User                                 | Time (GMT)           |
|--|--------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                     | 01 May 2021 12:43:47 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 15 Apr 2021 00:02:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)          | 21 Jan 2021 16:46:44 |
| User closed query 'Per CDM RQ: Response noted. However, Left Knee Replacement is not a Solicited Event per protocol. Please review and update, else clarify.' (Site from DM).  | (b) (4), (b) (6)                     | 18 Dec 2020 07:55:20 |
| Query 'Per CDM RQ: Response noted. However, Left Knee Replacement is not a Solicited Event per protocol. Please review and update, else clarify.' answered with 'updated' (Site from DM).  | Jennifer Molstead (b) (4)<br>(b) (4) | 17 Dec 2020 16:12:55 |
| DataPoint Un-verified.   | Jennifer Molstead (b) (4)<br>(b) (4) | 17 Dec 2020 16:12:44 |
| User entered 'No (N)' reason for change: Per Query Resolution  | Jennifer Molstead (b) (4)<br>(b) (4) | 17 Dec 2020 16:12:44 |
| User opened query 'Per CDM RQ: Response noted. However, Left Knee Replacement is not a Solicited Event per protocol. Please review and update, else clarify.' (Site from DM).  | (b) (4), (b) (6)                     | 08 Dec 2020 18:44:41 |
| User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification. | (b) (4), (b) (6)                     | 08 Dec 2020 18:44:41 |
| ' (Site from DM).  |                                      |                      |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:26:34

Was this medication taken for solicited event?

| Audit  | User                                   | Time (GMT)           |
|--|--|----------------------|
| Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification.<br />' answered with 'GIVEN BECAUSE OF LEFT KNEE REPLACEMENT' (Site from DM). | Traci Hull (b) (4)<br>(b) (4)          | 04 Dec 2020 21:16:02 |
| User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,) and medication started prior to ICF date/IP admin. Please review and update as appropriate. Otherwise, provide clarification.<br>' (Site from DM).  | (b) (4), (b) (6)<br>(b) (4)            | 04 Dec 2020 04:08:05 |
| DataPoint Verified.  | (b) (4), (b) (6)<br>(b) (4)<br>(b) (4) | 23 Nov 2020 22:10:42 |
| User entered 'Yes (Y)'   | Tammy Kohn (b) (4)<br>(b) (4)          | 23 Nov 2020 20:00:55 |
| DataPoint activated with code reason code Data required.   | Tammy Kohn (b) (4)<br>(b) (4)          | 23 Nov 2020 19:59:32 |
| DataPoint inactivated with code reason code Data not required.   | Tammy Kohn (b) (4)<br>(b) (4)          | 23 Nov 2020 19:58:34 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:26:34

[Separate Dosage Number \(derived\)](#)

| Audit  | User               | Time (GMT)           |
|--|--------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)   | 01 May 2021 12:43:47 |
| User entered '1'   | System             | 23 Nov 2020 20:00:55 |
| DataPoint activated with code reason code Data required.       | Tammy Kohn (b) (4) | 23 Nov 2020 19:59:32 |
| DataPoint inactivated with code reason code Data not required. | Tammy Kohn (b) (4) | 23 Nov 2020 19:58:34 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:26:34

[Interval Dosage Unit Number \(derived\)](#)

| Audit  | User               | Time (GMT)           |
|--|--------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)   | 01 May 2021 12:43:47 |
| User entered '1'   | System             | 23 Nov 2020 20:00:55 |
| DataPoint activated with code reason code Data required.       | Tammy Kohn (b) (4) | 23 Nov 2020 19:59:32 |
| DataPoint inactivated with code reason code Data not required. | Tammy Kohn (b) (4) | 23 Nov 2020 19:58:34 |

US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:26:34

[Interval Dosage Definition \(derived\)](#)

| Audit  | User               | Time (GMT)           |
|--|--------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)   | 01 May 2021 12:43:47 |
| User entered '804 (804)'                                       | System             | 23 Nov 2020 20:00:55 |
| DataPoint activated with code reason code Data required.       | Tammy Kohn (b) (4) | 23 Nov 2020 19:59:32 |
| DataPoint inactivated with code reason code Data not required. | Tammy Kohn (b) (4) | 23 Nov 2020 19:58:34 |



US3402139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:26:34

[Name of Medication](#)

| Audit   | User                                       | Time (GMT)           |
|---|--|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                           | 16 Apr 2021 16:49:01 |
| User signature succeeded.   | Frank Eder (b) (4)                         | 15 Apr 2021 00:02:45 |
| User coded data point as ATC:<br>MUSCULO-SKELETAL SYSTEM, ATC:<br>ANTIINFLAMMATORY AND ANTIRHEUMATIC<br>PRODUCTS, ATC: ANTIINFLAMMATORY AND<br>ANTIRHEUMATIC PRODUCTS,<br>NON-STEROIDS, ATC: OXICAMS, PRODUCT:<br>MELOXICAM - version<br>WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4)<br>(b) (4) | 31 Mar 2021 13:17:35 |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)            | 31 Mar 2021 13:17:35 |
| Data point term sent to Coder   | System                                     | 26 Mar 2021 13:44:31 |
| User entered 'MELOXICAM'  | Traci Hull (b) (4)<br>(b) (4)              | 26 Mar 2021 13:44:28 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:26:34**

[Prophylaxis](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)   | 16 Apr 2021 16:49:23 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Apr 2021 00:02:45 |
| User entered 'No (N)'     | (b) (4)            | 26 Mar 2021 13:44:28 |
|                           | Traci Hull (b) (4) |                      |
|                           | (b) (4)            |                      |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:26:34**

[Indication](#)

| Audit                              | User               | Time (GMT)           |
|------------------------------------|--------------------|----------------------|
| DataPoint Verified.                | (b) (4), (b) (6)   | 16 Apr 2021 16:49:25 |
| User signature succeeded.          | Frank Eder (b) (4) | 15 Apr 2021 00:02:45 |
| User entered 'LEFT KNEE ARTHRITIS' | Traci Hull (b) (4) | 26 Mar 2021 13:44:28 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:26:34**

[Dose per administration](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                         | 16 Apr 2021 16:49:27 |
| User signature succeeded. | Frank Eder (b) (4)                       | 15 Apr 2021 00:02:45 |
| User entered '7.5'        | (b) (4)<br>Traci Hull (b) (4)<br>(b) (4) | 26 Mar 2021 13:44:28 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:26:34**

[Dose unit](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                         | 16 Apr 2021 16:49:29 |
| User signature succeeded. | Frank Eder (b) (4)                       | 15 Apr 2021 00:02:45 |
| User entered 'mg (mg)'    | (b) (4)<br>Traci Hull (b) (4)<br>(b) (4) | 26 Mar 2021 13:44:28 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:26:34**

If dose unit is Other, specify

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)   | 16 Apr 2021 16:49:31 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Apr 2021 00:02:45 |
| User entered empty.       | (b) (4)            |                      |
|                           | Traci Hull (b) (4) | 26 Mar 2021 13:44:28 |
|                           | (b) (4)            |                      |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:26:34**

[Frequency](#)

| Audit                          | User               | Time (GMT)           |
|--------------------------------|--------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)   | 16 Apr 2021 16:49:33 |
| User signature succeeded.      | Frank Eder (b) (4) | 15 Apr 2021 00:02:45 |
| User entered 'as needed (PRN)' | (b) (4)            |                      |
|                                | Traci Hull (b) (4) | 26 Mar 2021 13:44:28 |
|                                | (b) (4)            |                      |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:26:34**

[If frequency is Other, specify](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 16 Apr 2021 16:49:35 |
| User signature succeeded. | Frank Eder (b) (4)            | 15 Apr 2021 00:02:45 |
| User entered empty.       | (b) (4)<br>Traci Hull (b) (4) | 26 Mar 2021 13:44:28 |



**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:26:34**

[Route of administration](#)

| Audit                      | User               | Time (GMT)           |
|----------------------------|--------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)   | 16 Apr 2021 16:49:37 |
| User signature succeeded.  | Frank Eder (b) (4) | 15 Apr 2021 00:02:45 |
| User entered 'Oral (ORAL)' | (b) (4)            | 26 Mar 2021 13:44:28 |
|                            | Traci Hull (b) (4) |                      |
|                            | (b) (4)            |                      |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:26:34**

[If route of administration is Other, specify](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)   | 16 Apr 2021 16:49:39 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Apr 2021 00:02:45 |
| User entered empty.       | Traci Hull (b) (4) | 26 Mar 2021 13:44:28 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:26:34**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User               | Time (GMT)           |
|----------------------------|--------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)   | 16 Apr 2021 16:49:41 |
| User signature succeeded.  | Frank Eder (b) (4) | 15 Apr 2021 00:02:45 |
| User entered '22 Mar 2021' | Traci Hull (b) (4) | 26 Mar 2021 13:44:28 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:26:34**

[Start date completely unknown](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                         | 16 Apr 2021 16:49:44 |
| User signature succeeded. | Frank Eder (b) (4)                       | 15 Apr 2021 00:02:45 |
| User entered '0'          | (b) (4)<br>Traci Hull (b) (4)<br>(b) (4) | 26 Mar 2021 13:44:28 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:26:34**

[Ongoing?](#)

| Audit                     | User                          | Time (GMT)           |
|---------------------------|-------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)              | 16 Apr 2021 16:49:50 |
| User signature succeeded. | Frank Eder (b) (4)            | 15 Apr 2021 00:02:45 |
| User entered 'Yes (Y)'    | (b) (4)<br>Traci Hull (b) (4) | 26 Mar 2021 13:44:28 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:26:34**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                         | 16 Apr 2021 16:49:52 |
| User signature succeeded. | Frank Eder (b) (4)                       | 15 Apr 2021 00:02:45 |
| User entered empty.       | (b) (4)<br>Traci Hull (b) (4)<br>(b) (4) | 26 Mar 2021 13:44:28 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:26:34**

[Was this medication taken for solicited event?](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                         | 16 Apr 2021 16:49:55 |
| User signature succeeded. | Frank Eder (b) (4)                       | 15 Apr 2021 00:02:45 |
| User entered 'No (N)'     | (b) (4)<br>Traci Hull (b) (4)<br>(b) (4) | 26 Mar 2021 13:44:28 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:26:34**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Mar 2021 13:44:28 |



**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Mar 2021 13:44:28 |

**US3402139**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:26:34**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Mar 2021 13:44:28 |

US3402139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:26:34

[Were any concomitant procedures performed?](#)

| Audit  | User                          | Time (GMT)           |
|--|-------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)              | 03 May 2021 06:32:36 |
| User signature succeeded.  | Frank Eder (b) (4)            | 08 Apr 2021 23:27:02 |
| User closed query 'Per source - subject had left knee replacement - for left knee arthritis on 12 Oct 2020. Please ' (Site from CRA).                  | (b) (4)<br>(b) (4), (b) (6)   | 24 Nov 2020 20:55:24 |
| DataPoint Verified.  | (b) (4), (b) (6)              | 24 Nov 2020 20:55:23 |
| Query 'Per source - subject had left knee replacement - for left knee arthritis on 12 Oct 2020. Please ' answered with 'data updated' (Site from CRA). | Tammy Kohn (b) (4)<br>(b) (4) | 23 Nov 2020 16:00:26 |
| DataPoint Un-verified.   | Tammy Kohn (b) (4)<br>(b) (4) | 23 Nov 2020 15:58:53 |
| User entered 'Yes (Y)' reason for change: Data Entry Error   | Tammy Kohn (b) (4)<br>(b) (4) | 23 Nov 2020 15:58:53 |
| User opened query 'Per source - subject had left knee replacement - for left knee arthritis on 12 Oct 2020. Please ' (Site from CRA).                  | (b) (4), (b) (6)              | 20 Nov 2020 19:57:50 |
| DataPoint Verified.  | (b) (4), (b) (6)              | 20 Nov 2020 19:54:58 |
| User entered 'No (N)'  | Traci Hull (b) (4)<br>(b) (4) | 03 Sep 2020 19:42:42 |

US3402139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:26:34

Procedure/Surgery date (*dd MMM yyyy*)

| Audit                      | User               | Time (GMT)           |
|----------------------------|--------------------|----------------------|
| User signature succeeded.  | Frank Eder (b) (4) | 08 Apr 2021 23:27:02 |
| DataPoint Verified.        | (b) (4)            |                      |
|                            | (b) (4), (b) (6)   | 23 Nov 2020 22:21:15 |
|                            |                    |                      |
| User entered '12 Oct 2020' | Tammy Kohn (b) (4) | 23 Nov 2020 16:00:11 |
|                            | (b) (4)            |                      |

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:26:34

[Procedure/Surgery](#)

| Audit                                | User               | Time (GMT)           |
|--------------------------------------|--------------------|----------------------|
| User signature succeeded.            | Frank Eder (b) (4) | 08 Apr 2021 23:27:02 |
| DataPoint Verified.                  | (b) (4)            |                      |
|                                      | (b) (4), (b) (6)   | 23 Nov 2020 22:21:15 |
|                                      |                    |                      |
| User entered 'left knee replacement' | Tammy Kohn (b) (4) | 23 Nov 2020 16:00:11 |
|                                      | (b) (4)            |                      |

US3402139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:26:34

[Indication](#)

| Audit   | User                      | Time (GMT)           |
|---|---------------------------|----------------------|
| User signature succeeded.   | Frank Eder (b) (4)        | 08 Apr 2021 23:27:02 |
| DataPoint Verified.   | (b) (4)                   |                      |
|   | (b) (4), (b) (6)          | 21 Jan 2021 16:44:13 |
| User closed query 'Per DM CLR: Indication = OTHER, however, the noted medical condition in the Other, specify field is recorded in the AE eCRF page. Please reconcile and confirm if indication should be recorded as one of the available options (i.e. Adverse Event) as appropriate, otherwise clarify.' (Site from DM).             | (b) (4), (b) (6)          | 18 Dec 2020 07:19:44 |
| Query 'Per DM CLR: Indication = OTHER, however, the noted medical condition in the Other, specify field is recorded in the AE eCRF page. Please reconcile and confirm if indication should be recorded as one of the available options (i.e. Adverse Event) as appropriate, otherwise clarify.' answered with 'updated' (Site from DM). | Jennifer Molstead (b) (4) | 17 Dec 2020 16:08:53 |
|   | (b) (4)                   |                      |
| DataPoint Un-verified.  | Jennifer Molstead (b) (4) | 17 Dec 2020 16:08:42 |
|   | (b) (4)                   |                      |
| User entered 'Adverse Event (AE)' reason for change: Per Query Resolution   | Jennifer Molstead (b) (4) | 17 Dec 2020 16:08:42 |
|   | (b) (4)                   |                      |
| User opened query 'Per DM CLR: Indication = OTHER, however, the noted medical condition in the Other, specify field is recorded in the AE eCRF page. Please reconcile and confirm if indication should be recorded as one of the available options (i.e. Adverse Event) as appropriate, otherwise clarify.' (Site from DM).             | (b) (4), (b) (6)          | 16 Dec 2020 08:13:42 |
|   |                           |                      |
| DataPoint Verified.   | (b) (4), (b) (6)          | 23 Nov 2020 22:21:15 |
|   |                           |                      |
|   |                           |                      |
| User entered 'Other (OTHER)'  | Tammy Kohn (b) (4)        | 23 Nov 2020 16:00:11 |
|   | (b) (4)                   |                      |

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:26:34

If indication is Other, specify

| Audit   | User                      | Time (GMT)           |
|---|---------------------------|----------------------|
| User signature succeeded.                                       | Frank Eder (b) (4)        | 08 Apr 2021 23:27:02 |
| DataPoint Verified.   | (b) (4)                   |                      |
|   | (b) (4), (b) (6)          | 21 Jan 2021 16:44:22 |
| DataPoint Un-verified.  | Jennifer Molstead (b) (4) | 17 Dec 2020 16:08:42 |
|   | (b) (4)                   |                      |
| User entered empty; reason for change Per Query Resolution      | Jennifer Molstead (b) (4) | 17 Dec 2020 16:08:42 |
| DataPoint Verified.   | (b) (4)                   |                      |
|   | (b) (4), (b) (6)          | 23 Nov 2020 22:21:15 |
|   |                           |                      |
| User entered 'left knee replacement due to left knee arthritis' | Tammy Kohn (b) (4)        | 23 Nov 2020 16:00:11 |
|   | (b) (4)                   |                      |

US3402139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:26:34

Procedure/Surgery date (*dd MMM yyyy*)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 08:26:21 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 08 Apr 2021 23:27:02 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 23 Nov 2020 22:21:15 |
| User entered '13 Oct 2020' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:08:02 |



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:26:34

[Procedure/Surgery](#)

| Audit                               | User                                 | Time (GMT)           |
|-------------------------------------|--------------------------------------|----------------------|
| Data hard locked.                   | (b) (4), (b) (6)                     | 01 May 2021 08:26:21 |
| User signature succeeded.           | Frank Eder (b) (4)                   | 08 Apr 2021 23:27:02 |
| DataPoint Verified.                 | (b) (4)<br>(b) (4), (b) (6)          | 23 Nov 2020 22:21:15 |
| User entered 'complete Blood Count' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:08:02 |

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:26:34

[Indication](#)

| Audit                             | User                                 | Time (GMT)           |
|-----------------------------------|--------------------------------------|----------------------|
| Data hard locked.                 | (b) (4), (b) (6)                     | 01 May 2021 08:26:21 |
| User signature succeeded.         | Frank Eder (b) (4)                   | 08 Apr 2021 23:27:02 |
| DataPoint Verified.               | (b) (4)<br>(b) (4), (b) (6)          | 23 Nov 2020 22:21:15 |
| User entered 'Adverse Event (AE)' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:08:02 |

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:26:34

If indication is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 08:26:21 |
| User signature succeeded. | Frank Eder (b) (4)                   | 08 Apr 2021 23:27:02 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 23 Nov 2020 22:21:15 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:08:02 |

US3402139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:26:34

Procedure/Surgery date (*dd MMM yyyy*)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                     | 01 May 2021 08:26:22 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 08 Apr 2021 23:27:02 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)          | 23 Nov 2020 22:21:15 |
| User entered '14 Oct 2020' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:08:23 |

US3402139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:26:34

[Procedure/Surgery](#)

| Audit                               | User                                 | Time (GMT)           |
|-------------------------------------|--------------------------------------|----------------------|
| Data hard locked.                   | (b) (4), (b) (6)                     | 01 May 2021 08:26:22 |
| User signature succeeded.           | Frank Eder (b) (4)                   | 08 Apr 2021 23:27:02 |
| DataPoint Verified.                 | (b) (4)<br>(b) (4), (b) (6)          | 23 Nov 2020 22:21:15 |
| User entered 'Complete Blood Count' | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:08:23 |

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:26:34

[Indication](#)

| Audit  | User                                 | Time (GMT)           |
|--|--------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                     | 01 May 2021 08:26:22 |
| User signature succeeded.  | Frank Eder (b) (4)                   | 08 Apr 2021 23:27:02 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)          | 23 Nov 2020 22:21:15 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                               | 23 Nov 2020 18:08:28 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                               | 23 Nov 2020 18:08:28 |
| User entered 'Adverse Event (AE)' reason for change: Data Entry Error                  | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:08:28 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                               | 23 Nov 2020 18:08:23 |
| User entered empty.  | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:08:23 |

US3402139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:26:34

If indication is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 01 May 2021 08:26:22 |
| User signature succeeded. | Frank Eder (b) (4)                   | 08 Apr 2021 23:27:02 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)          | 23 Nov 2020 22:21:15 |
| User entered empty.       | Jennifer Molstead (b) (4)<br>(b) (4) | 23 Nov 2020 18:08:23 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[SAEID](#)

| Audit   | User               | Time (GMT)           |
|---|--------------------|----------------------|
| User signature succeeded.                             | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.                                   | (b) (4)            |                      |
|   | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.                                  | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|   |                    |                      |
| User entered<br>'USA-US059-2020-MRNA-1273-P301000014' | System             | 27 Oct 2020 14:19:05 |



**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

**Serious**

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'Yes (Y)'    | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Death](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'No (N)'     | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Life threatening](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'No (N)'     | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'Yes (Y)'    | System             | 27 Oct 2020 14:19:05 |

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:34

[Persistent or significant disability or incapacity](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
|                           | (b) (4)            |                      |
| DataPoint Verified.       | (b) (4), (b) (6)   | 21 Jan 2021 16:48:58 |
|                           |                    |                      |
| Un-reviewed for Safety.   | System             | 17 Dec 2020 19:09:58 |
| User entered 'No (N)'     | System             | 17 Dec 2020 19:09:58 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 02 Dec 2020 16:50:51 |
|                           |                    |                      |
| Un-reviewed for Safety.   | System             | 02 Dec 2020 16:50:19 |
| DataPoint Un-verified.    | System             | 02 Dec 2020 16:50:19 |
| User entered 'Yes (Y)'    | System             | 02 Dec 2020 16:50:19 |
| DataPoint Verified.       | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
|                           |                    |                      |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'No (N)'     | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Congenital anomaly or birth defect](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'No (N)'     | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Other medically important event](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'No (N)'     | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Investigator's First Name](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'Frank'      | System             | 27 Oct 2020 14:19:05 |



US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:34

[Investigator's Last Name](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'Eder'       | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Site Address: Street](#)

| Audit                                  | User               | Time (GMT)           |
|--|--------------------|----------------------|
| User signature succeeded.              | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.                    | (b) (4)            |                      |
|  | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.                   | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|  |                    |                      |
| User entered '1290 Upper Front Street' | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Site Address: City](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'Binghamton' | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Site Address: State](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'NY'         | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Site Address: Postal Code](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered '13901'      | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)          | 26 Apr 2021 01:45:47 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 18 Nov 2020 14:45:02 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 06 Nov 2020 23:02:06 |
| User entered 'US'         | System                      | 27 Oct 2020 14:25:57 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '6' | System | 17 Dec 2020 19:09:58 |
| User entered '5' | System | 02 Dec 2020 16:51:04 |
| User entered '4' | System | 24 Nov 2020 13:43:10 |
| User entered '3' | System | 18 Nov 2020 14:45:11 |
| User entered '2' | System | 09 Nov 2020 19:27:50 |
| User entered '1' | System | 27 Oct 2020 14:25:57 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[SAEID](#)

| Audit   | User               | Time (GMT)           |
|---|--------------------|----------------------|
| User signature succeeded.                             | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.                                   | (b) (4)            |                      |
|   | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.                                  | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|   |                    |                      |
| User entered<br>'USA-US059-2020-MRNA-1273-P301000014' | System             | 27 Oct 2020 14:19:05 |



**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

**Serious**

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'Yes (Y)'    | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Death](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'No (N)'     | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Life threatening](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'No (N)'     | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'Yes (Y)'    | System             | 27 Oct 2020 14:19:05 |

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:34

[Persistent or significant disability or incapacity](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
|                           | (b) (4)            |                      |
| DataPoint Verified.       | (b) (4), (b) (6)   | 21 Jan 2021 16:48:58 |
|                           |                    |                      |
| Un-reviewed for Safety.   | System             | 17 Dec 2020 19:09:58 |
| User entered 'No (N)'     | System             | 17 Dec 2020 19:09:58 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 02 Dec 2020 16:50:51 |
|                           |                    |                      |
| Un-reviewed for Safety.   | System             | 02 Dec 2020 16:50:19 |
| DataPoint Un-verified.    | System             | 02 Dec 2020 16:50:19 |
| User entered 'Yes (Y)'    | System             | 02 Dec 2020 16:50:19 |
| DataPoint Verified.       | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
|                           |                    |                      |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'No (N)'     | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Congenital anomaly or birth defect](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'No (N)'     | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Other medically important event](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'No (N)'     | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Investigator's First Name](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'Frank'      | System             | 27 Oct 2020 14:19:05 |



US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:34

[Investigator's Last Name](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'Eder'       | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Site Address: Street](#)

| Audit                                  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.              | Frank Eder (b) (4)          | 26 Apr 2021 01:45:47 |
| DataPoint Verified.                    | (b) (4)<br>(b) (4), (b) (6) | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.                   | (b) (4), (b) (6)            | 27 Oct 2020 14:25:50 |
| User entered '1290 Upper Front Street' | System                      | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Site Address: City](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'Binghamton' | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Site Address: State](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'NY'         | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Site Address: Postal Code](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered '13901'      | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)          | 26 Apr 2021 01:45:47 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 18 Nov 2020 14:45:02 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 06 Nov 2020 23:02:06 |
| User entered 'US'         | System                      | 27 Oct 2020 14:25:57 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '6' | System | 17 Dec 2020 19:09:58 |
| User entered '5' | System | 02 Dec 2020 16:51:04 |
| User entered '4' | System | 24 Nov 2020 13:43:10 |
| User entered '3' | System | 18 Nov 2020 14:45:11 |
| User entered '2' | System | 09 Nov 2020 19:27:50 |
| User entered '1' | System | 27 Oct 2020 14:25:57 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:26:34**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                        | Time (GMT)           |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded.        | Frank Eder (b) (4)          | 26 Apr 2021 01:45:47 |
| DataPoint Verified.              | (b) (4)<br>(b) (4), (b) (6) | 06 Nov 2020 23:02:06 |
| User entered '27/Oct/2020 10:25' | System                      | 27 Oct 2020 14:25:57 |



US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:26:34

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)          | 26 Apr 2021 01:45:47 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 18 Nov 2020 14:45:02 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 06 Nov 2020 23:02:06 |
| User entered 'I'          | (b) (4), (b) (6)            | 27 Oct 2020 14:25:57 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[SAEID](#)

| Audit   | User               | Time (GMT)           |
|---|--------------------|----------------------|
| User signature succeeded.                             | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.                                   | (b) (4)            |                      |
|   | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.                                  | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|   |                    |                      |
| User entered<br>'USA-US059-2020-MRNA-1273-P301000014' | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

**Serious**

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'Yes (Y)'    | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Death](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'No (N)'     | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Life threatening](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'No (N)'     | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'Yes (Y)'    | System             | 27 Oct 2020 14:19:05 |

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:34

[Persistent or significant disability or incapacity](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
|                           | (b) (4)            |                      |
| DataPoint Verified.       | (b) (4), (b) (6)   | 21 Jan 2021 16:48:58 |
|                           |                    |                      |
| Un-reviewed for Safety.   | System             | 17 Dec 2020 19:09:58 |
| User entered 'No (N)'     | System             | 17 Dec 2020 19:09:58 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 02 Dec 2020 16:50:51 |
|                           |                    |                      |
| Un-reviewed for Safety.   | System             | 02 Dec 2020 16:50:19 |
| DataPoint Un-verified.    | System             | 02 Dec 2020 16:50:19 |
| User entered 'Yes (Y)'    | System             | 02 Dec 2020 16:50:19 |
| DataPoint Verified.       | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
|                           |                    |                      |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'No (N)'     | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Congenital anomaly or birth defect](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'No (N)'     | System             | 27 Oct 2020 14:19:05 |



**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Other medically important event](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'No (N)'     | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Investigator's First Name](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'Frank'      | System             | 27 Oct 2020 14:19:05 |

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:34

[Investigator's Last Name](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'Eder'       | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Site Address: Street](#)

| Audit                                  | User               | Time (GMT)           |
|--|--------------------|----------------------|
| User signature succeeded.              | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.                    | (b) (4)            |                      |
|  | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.                   | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|  |                    |                      |
| User entered '1290 Upper Front Street' | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Site Address: City](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'Binghamton' | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Site Address: State](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'NY'         | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Site Address: Postal Code](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered '13901'      | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)          | 26 Apr 2021 01:45:47 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 18 Nov 2020 14:45:02 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 06 Nov 2020 23:02:06 |
| User entered 'US'         | System                      | 27 Oct 2020 14:25:57 |



**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '6' | System | 17 Dec 2020 19:09:58 |
| User entered '5' | System | 02 Dec 2020 16:51:04 |
| User entered '4' | System | 24 Nov 2020 13:43:10 |
| User entered '3' | System | 18 Nov 2020 14:45:11 |
| User entered '2' | System | 09 Nov 2020 19:27:50 |
| User entered '1' | System | 27 Oct 2020 14:25:57 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 17:26:34**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                        | Time (GMT)           |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded.        | Frank Eder (b) (4)          | 26 Apr 2021 01:45:47 |
| DataPoint Verified.              | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 16:51:39 |
| User entered '09/Nov/2020 14:27' | System                      | 09 Nov 2020 19:27:50 |

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:26:34

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)          | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 16:51:41 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 18 Nov 2020 14:45:02 |
| User entered 'I'          | (b) (4), (b) (6)            | 09 Nov 2020 19:27:50 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[SAEID](#)

| Audit   | User               | Time (GMT)           |
|---|--------------------|----------------------|
| User signature succeeded.                             | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.                                   | (b) (4)            |                      |
|   | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.                                  | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|   |                    |                      |
| User entered<br>'USA-US059-2020-MRNA-1273-P301000014' | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

**Serious**

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'Yes (Y)'    | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Death](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'No (N)'     | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Life threatening](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'No (N)'     | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'Yes (Y)'    | System             | 27 Oct 2020 14:19:05 |



US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:34

[Persistent or significant disability or incapacity](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 21 Jan 2021 16:48:58 |
| Un-reviewed for Safety.   | System             | 17 Dec 2020 19:09:58 |
| User entered 'No (N)'     | System             | 17 Dec 2020 19:09:58 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 02 Dec 2020 16:50:51 |
| Un-reviewed for Safety.   | System             | 02 Dec 2020 16:50:19 |
| DataPoint Un-verified.    | System             | 02 Dec 2020 16:50:19 |
| User entered 'Yes (Y)'    | System             | 02 Dec 2020 16:50:19 |
| DataPoint Verified.       | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
| User entered 'No (N)'     | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Congenital anomaly or birth defect](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'No (N)'     | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Other medically important event](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'No (N)'     | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Investigator's First Name](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'Frank'      | System             | 27 Oct 2020 14:19:05 |

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:34

[Investigator's Last Name](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'Eder'       | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Site Address: Street](#)

| Audit                                  | User               | Time (GMT)           |
|--|--------------------|----------------------|
| User signature succeeded.              | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.                    | (b) (4)            |                      |
|  | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.                   | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|  |                    |                      |
| User entered '1290 Upper Front Street' | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Site Address: City](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'Binghamton' | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Site Address: State](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'NY'         | System             | 27 Oct 2020 14:19:05 |



**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Site Address: Postal Code](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered '13901'      | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)          | 26 Apr 2021 01:45:47 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 18 Nov 2020 14:45:02 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 06 Nov 2020 23:02:06 |
| User entered 'US'         | System                      | 27 Oct 2020 14:25:57 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '6' | System | 17 Dec 2020 19:09:58 |
| User entered '5' | System | 02 Dec 2020 16:51:04 |
| User entered '4' | System | 24 Nov 2020 13:43:10 |
| User entered '3' | System | 18 Nov 2020 14:45:11 |
| User entered '2' | System | 09 Nov 2020 19:27:50 |
| User entered '1' | System | 27 Oct 2020 14:25:57 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 17:26:34**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                        | Time (GMT)           |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded.        | Frank Eder (b) (4)          | 26 Apr 2021 01:45:47 |
| DataPoint Verified.              | (b) (4)<br>(b) (4), (b) (6) | 20 Nov 2020 20:20:37 |
| User entered '18/Nov/2020 09:45' | System                      | 18 Nov 2020 14:45:11 |

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:26:34

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)          | 26 Apr 2021 01:45:47 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 13:40:01 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Nov 2020 20:20:42 |
| User entered 'I'          | (b) (4), (b) (6)            | 18 Nov 2020 14:45:11 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[SAEID](#)

| Audit   | User               | Time (GMT)           |
|---|--------------------|----------------------|
| User signature succeeded.                             | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.                                   | (b) (4)            |                      |
|   | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.                                  | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|   |                    |                      |
| User entered<br>'USA-US059-2020-MRNA-1273-P301000014' | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

**Serious**

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'Yes (Y)'    | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Death](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'No (N)'     | System             | 27 Oct 2020 14:19:05 |



**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Life threatening](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'No (N)'     | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'Yes (Y)'    | System             | 27 Oct 2020 14:19:05 |

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:34

[Persistent or significant disability or incapacity](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
|                           | (b) (4)            |                      |
| DataPoint Verified.       | (b) (4), (b) (6)   | 21 Jan 2021 16:48:58 |
|                           |                    |                      |
| Un-reviewed for Safety.   | System             | 17 Dec 2020 19:09:58 |
| User entered 'No (N)'     | System             | 17 Dec 2020 19:09:58 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 02 Dec 2020 16:50:51 |
|                           |                    |                      |
| Un-reviewed for Safety.   | System             | 02 Dec 2020 16:50:19 |
| DataPoint Un-verified.    | System             | 02 Dec 2020 16:50:19 |
| User entered 'Yes (Y)'    | System             | 02 Dec 2020 16:50:19 |
| DataPoint Verified.       | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
|                           |                    |                      |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'No (N)'     | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Congenital anomaly or birth defect](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'No (N)'     | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Other medically important event](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'No (N)'     | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Investigator's First Name](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'Frank'      | System             | 27 Oct 2020 14:19:05 |

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:34

[Investigator's Last Name](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'Eder'       | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Site Address: Street](#)

| Audit                                  | User               | Time (GMT)           |
|--|--------------------|----------------------|
| User signature succeeded.              | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.                    | (b) (4)            |                      |
|  | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.                   | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|  |                    |                      |
| User entered '1290 Upper Front Street' | System             | 27 Oct 2020 14:19:05 |



**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Site Address: City](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'Binghamton' | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Site Address: State](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'NY'         | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Site Address: Postal Code](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered '13901'      | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)          | 26 Apr 2021 01:45:47 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 18 Nov 2020 14:45:02 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 06 Nov 2020 23:02:06 |
| User entered 'US'         | System                      | 27 Oct 2020 14:25:57 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '6' | System | 17 Dec 2020 19:09:58 |
| User entered '5' | System | 02 Dec 2020 16:51:04 |
| User entered '4' | System | 24 Nov 2020 13:43:10 |
| User entered '3' | System | 18 Nov 2020 14:45:11 |
| User entered '2' | System | 09 Nov 2020 19:27:50 |
| User entered '1' | System | 27 Oct 2020 14:25:57 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 17:26:34**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                        | Time (GMT)           |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded.        | Frank Eder (b) (4)          | 26 Apr 2021 01:45:47 |
| DataPoint Verified.              | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 16:50:51 |
| User entered '24/Nov/2020 08:43' | System                      | 24 Nov 2020 13:43:10 |

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:26:34

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 21 Jan 2021 16:50:53 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 02 Dec 2020 16:50:51 |
| User entered 'I'          | (b) (4), (b) (6)   | 24 Nov 2020 13:43:10 |
|                           |                    |                      |
|                           |                    |                      |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[SAEID](#)

| Audit   | User               | Time (GMT)           |
|---|--------------------|----------------------|
| User signature succeeded.                             | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.                                   | (b) (4)            |                      |
|   | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.                                  | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|   |                    |                      |
| User entered<br>'USA-US059-2020-MRNA-1273-P301000014' | System             | 27 Oct 2020 14:19:05 |



**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

**Serious**

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'Yes (Y)'    | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Death](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'No (N)'     | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Life threatening](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'No (N)'     | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'Yes (Y)'    | System             | 27 Oct 2020 14:19:05 |

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:34

[Persistent or significant disability or incapacity](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
|                           | (b) (4)            |                      |
| DataPoint Verified.       | (b) (4), (b) (6)   | 21 Jan 2021 16:48:58 |
|                           |                    |                      |
| Un-reviewed for Safety.   | System             | 17 Dec 2020 19:09:58 |
| User entered 'No (N)'     | System             | 17 Dec 2020 19:09:58 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 02 Dec 2020 16:50:51 |
|                           |                    |                      |
| Un-reviewed for Safety.   | System             | 02 Dec 2020 16:50:19 |
| DataPoint Un-verified.    | System             | 02 Dec 2020 16:50:19 |
| User entered 'Yes (Y)'    | System             | 02 Dec 2020 16:50:19 |
| DataPoint Verified.       | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
|                           |                    |                      |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'No (N)'     | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Congenital anomaly or birth defect](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'No (N)'     | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Other medically important event](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'No (N)'     | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Investigator's First Name](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'Frank'      | System             | 27 Oct 2020 14:19:05 |



**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Investigator's Last Name](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'Eder'       | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Site Address: Street](#)

| Audit                                  | User               | Time (GMT)           |
|--|--------------------|----------------------|
| User signature succeeded.              | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.                    | (b) (4)            |                      |
|  | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.                   | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|  |                    |                      |
| User entered '1290 Upper Front Street' | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Site Address: City](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'Binghamton' | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Site Address: State](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'NY'         | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Site Address: Postal Code](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered '13901'      | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)          | 26 Apr 2021 01:45:47 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 18 Nov 2020 14:45:02 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 06 Nov 2020 23:02:06 |
| User entered 'US'         | System                      | 27 Oct 2020 14:25:57 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '6' | System | 17 Dec 2020 19:09:58 |
| User entered '5' | System | 02 Dec 2020 16:51:04 |
| User entered '4' | System | 24 Nov 2020 13:43:10 |
| User entered '3' | System | 18 Nov 2020 14:45:11 |
| User entered '2' | System | 09 Nov 2020 19:27:50 |
| User entered '1' | System | 27 Oct 2020 14:25:57 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 17:26:34**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                        | Time (GMT)           |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded.        | Frank Eder (b) (4)          | 26 Apr 2021 01:45:47 |
| DataPoint Verified.              | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 16:50:59 |
| User entered '02/Dec/2020 11:51' | System                      | 02 Dec 2020 16:51:04 |



US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:26:34

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 21 Jan 2021 16:51:03 |
| User entered 'I'          | (b) (4), (b) (6)   | 02 Dec 2020 16:51:04 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[SAEID](#)

| Audit   | User               | Time (GMT)           |
|---|--------------------|----------------------|
| User signature succeeded.                             | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.                                   | (b) (4)            |                      |
|   | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.                                  | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|   |                    |                      |
| User entered<br>'USA-US059-2020-MRNA-1273-P301000014' | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

**Serious**

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'Yes (Y)'    | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Death](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'No (N)'     | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Life threatening](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'No (N)'     | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'Yes (Y)'    | System             | 27 Oct 2020 14:19:05 |

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:34

[Persistent or significant disability or incapacity](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
|                           | (b) (4)            |                      |
| DataPoint Verified.       | (b) (4), (b) (6)   | 21 Jan 2021 16:48:58 |
|                           |                    |                      |
| Un-reviewed for Safety.   | System             | 17 Dec 2020 19:09:58 |
| User entered 'No (N)'     | System             | 17 Dec 2020 19:09:58 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 02 Dec 2020 16:50:51 |
|                           |                    |                      |
| Un-reviewed for Safety.   | System             | 02 Dec 2020 16:50:19 |
| DataPoint Un-verified.    | System             | 02 Dec 2020 16:50:19 |
| User entered 'Yes (Y)'    | System             | 02 Dec 2020 16:50:19 |
| DataPoint Verified.       | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
|                           |                    |                      |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'No (N)'     | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Congenital anomaly or birth defect](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'No (N)'     | System             | 27 Oct 2020 14:19:05 |



**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Other medically important event](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'No (N)'     | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Investigator's First Name](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'Frank'      | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Investigator's Last Name](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'Eder'       | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Site Address: Street](#)

| Audit                                  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.              | Frank Eder (b) (4)          | 26 Apr 2021 01:45:47 |
| DataPoint Verified.                    | (b) (4)<br>(b) (4), (b) (6) | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.                   | (b) (4), (b) (6)            | 27 Oct 2020 14:25:50 |
| User entered '1290 Upper Front Street' | System                      | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Site Address: City](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'Binghamton' | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Site Address: State](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered 'NY'         | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Site Address: Postal Code](#)

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 06 Nov 2020 23:02:06 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 27 Oct 2020 14:25:50 |
|                           |                    |                      |
| User entered '13901'      | System             | 27 Oct 2020 14:19:05 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4)          | 26 Apr 2021 01:45:47 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 18 Nov 2020 14:45:02 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 06 Nov 2020 23:02:06 |
| User entered 'US'         | System                      | 27 Oct 2020 14:25:57 |



**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:26:34**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '6' | System | 17 Dec 2020 19:09:58 |
| User entered '5' | System | 02 Dec 2020 16:51:04 |
| User entered '4' | System | 24 Nov 2020 13:43:10 |
| User entered '3' | System | 18 Nov 2020 14:45:11 |
| User entered '2' | System | 09 Nov 2020 19:27:50 |
| User entered '1' | System | 27 Oct 2020 14:25:57 |

**US3402139**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000014**

**Form: Safety Report Form (6)**

**Generated On: 09 Jun 2021 17:26:34**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                        | Time (GMT)           |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded.        | Frank Eder (b) (4)          | 26 Apr 2021 01:45:47 |
| DataPoint Verified.              | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 16:51:07 |
| User entered '17/Dec/2020 14:09' | System                      | 17 Dec 2020 19:09:58 |

US3402139

Folder: SAE USA-US059-2020-MRNA-1273-P301000014

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:26:34

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User               | Time (GMT)           |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 01:45:47 |
| DataPoint Verified.       | (b) (4)            |                      |
|                           | (b) (4), (b) (6)   | 21 Jan 2021 16:51:09 |
| Reviewed for Safety.      | (b) (4), (b) (6)   | 17 Dec 2020 19:10:04 |
|                           |                    |                      |
| User entered 'I'          | (b) (4), (b) (6)   | 17 Dec 2020 19:09:58 |
|                           |                    |                      |
|                           |                    |                      |