

US3602123 (Prod: Hackensack University Medical Center)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:13:32

All time stamps listed in this document are displayed in GMT

US3602123

Form: Participant Creation

Data signed: (b) (4) 05 Apr 2021 21:29:34

Generated On: 10 Jun 2021 09:13:32

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Participant ID

US3602123

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

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US3602123

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 21:30:05

Generated On: 10 Jun 2021 09:13:32

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 02 OCT 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | SCRN                                    |

US3602123

Folder: Screening

Form: Demographics

Data signed: (b) (4) 05 Apr 2021 21:30:05

Generated On: 10 Jun 2021 09:13:32

|   |  |
|---|--|
| Date of Birth (MMM yyyy)                  | (b) (6) 1973   |
| Age                                       | 46   |
| Age Units                                 | YEARS  |
| Age (Derived)                             | 46   |
| Sex                                       | Female <input checked="" type="radio"/><br>Male <input type="radio"/>  |
| Ethnicity                                 | Hispanic or Latino <input checked="" type="radio"/><br>Not Hispanic or Latino <input type="radio"/><br>Not Reported <input type="radio"/><br>Unknown <input type="radio"/> |
| Race (Check All That Apply)               |  |
| White                                     | True   |
| Black                                     | False  |
| Asian                                     | False  |
| American Indian or Alaska Native          | False  |
| Native Hawaiian or other Pacific Islander | False  |
| Other                                     | False  |
| If race is Other, specify _____           |  |
| Unknown                                   | False  |
| Not reported                              | False  |

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 05 Apr 2021 21:30:05

Generated On: 10 Jun 2021 09:13:32

|   |  |
|---|--|
| Date of Informed Consent ( <i>dd MMM yyyy</i> ) | 2 OCT 2020   |
| Month and Year of Informed Consent (derived)    | OCT 2020   |
| Year of Informed Consent (derived)              | 2020   |
| Protocol Version                                | Amendment 1 <input type="radio"/><br>Amendment 2 <input type="radio"/><br>Amendment 3 <input checked="" type="radio"/><br>Amendment 4 <input type="radio"/><br>Amendment 5 <input type="radio"/> |
| Was participant enrolled in the study?          | Yes <input checked="" type="radio"/><br>No <input type="radio"/>   |
| If No, indicate reason for screen fail          | Withdrew Consent <input type="radio"/><br>Inclusion/Exclusion <input type="radio"/><br>Cohort Full <input type="radio"/><br>Other <input type="radio"/>  |
| If reason for screen fail is Other, specify     |  |
| Was this participant screened previously?       | Yes <input type="radio"/><br>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) 05 Apr 2021 21:30:05

Generated On: 10 Jun 2021 09:13:32

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 05 Apr 2021 21:30:05

Generated On: 10 Jun 2021 09:13:32

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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) 02 May 2021 01:32:34

Generated On: 10 Jun 2021 09:13:32

|   |  |
|---|--|
| Condition   | HYPERTENSION CONTROLLED<br>WITH ORAL MEDICATION                  |
| Start date (dd MMM yyyy)                          | UN UNK 2018  |
| 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 2018   |
| Start Year (derived)                              | 2018   |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 02 May 2021 01:32:34

Generated On: 10 Jun 2021 09:13:32

|   |  |
|---|--|
| Condition   | IMMUNE THROMBOCYTOPENIA  |
| Start date (dd MMM yyyy)                                | UN UNK 1999  |
| 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 1999   |
| Start Year (derived)                                    | 1999   |
| Stop Month and Year (derived)                           | _____  |
| Stop Year (derived)                                     | _____  |

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 02 May 2021 01:32:34

Generated On: 10 Jun 2021 09:13:32

|   |  |
|---|--|
| Condition   | SPLENECTOMY  |
| Start date (dd MMM yyyy)                          | UN UNK 2000  |
| Start date completely unknown                     | False  |
| Condition ongoing at study entry                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2000  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JAN 2000   |
| Start Year (derived)                              | 2000   |
| Stop Month and Year (derived)                     | JAN 2000   |
| Stop Year (derived)                               | 2000   |

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 02 May 2021 01:32:34

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|   |  |
|---|--|
| Condition   | C-SECTION  |
| Start date (dd MMM yyyy)                          | UN UNK 1999  |
| Start date completely unknown                     | False  |
| Condition ongoing at study entry                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 1999  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JAN 1999   |
| Start Year (derived)                              | 1999   |
| Stop Month and Year (derived)                     | JAN 1999   |
| Stop Year (derived)                               | 1999   |

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 02 May 2021 01:32:34

Generated On: 10 Jun 2021 09:13:32

|   |  |
|---|--|
| Condition   | CHOLYCYSTECTOMY  |
| Start date (dd MMM yyyy)                          | UN UNK 2000  |
| Start date completely unknown                     | False  |
| Condition ongoing at study entry                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2000  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JAN 2000   |
| Start Year (derived)                              | 2000   |
| Stop Month and Year (derived)                     | JAN 2000   |
| Stop Year (derived)                               | 2000   |

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 02 May 2021 01:32:34

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|   |  |
|---|--|
| Condition   | BREAST AUGMENTATION  |
| Start date (dd MMM yyyy)                          | UN UNK 2020  |
| Start date completely unknown                     | False  |
| Condition ongoing at study entry                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2020  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JAN 2020   |
| Start Year (derived)                              | 2020   |
| Stop Month and Year (derived)                     | JAN 2020   |
| Stop Year (derived)                               | 2020   |

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 02 May 2021 01:32:34

Generated On: 10 Jun 2021 09:13:32

|   |  |
|---|--|
| Condition   | SEASONAL ALLERGIES   |
| Start date (dd MMM yyyy)                                | UN UNK 2018  |
| 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 2018   |
| Start Year (derived)                                    | 2018   |
| Stop Month and Year (derived)                           | _____  |
| Stop Year (derived)                                     | _____  |

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 02 May 2021 01:32:34

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|   |  |
|---|--|
| Condition   | BORDERLINE LOW VITAMIN D<br>DEFICIENCY                           |
| Start date (dd MMM yyyy)                                | UN UNK 2018  |
| 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 2018   |
| Start Year (derived)                                    | 2018   |
| Stop Month and Year (derived)                           | _____  |
| Stop Year (derived)                                     | _____  |

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 02 May 2021 01:32:34

Generated On: 10 Jun 2021 09:13:32

|   |  |
|---|--|
| Condition   | BORDERLINE HIGH<br>CHOLESTEROL                                   |
| Start date (dd MMM yyyy)                                | UN UNK 2018  |
| 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 2018   |
| Start Year (derived)                                    | 2018   |
| Stop Month and Year (derived)                           | _____  |
| Stop Year (derived)                                     | _____  |



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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 21:30:05

Generated On: 10 Jun 2021 09:13:32

|   |                                      |
|---|--------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/> |
|   | No <input type="radio"/>             |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 2 OCT 2020                           |
| Time of assessment ( <i>00:00-23:59</i> ) | 13:16 (24 HR)                        |
| Vital Signs Date and Time (derived)       | 2 OCT 2020 13:16                     |
| Height ( <i>xxx.x</i> )                   | 65 in                                |
| Weight ( <i>xxx.x</i> )                   | 151 lb                               |
| BMI ( <i>xxx.x</i> )                      | 25.18025 kg/m <sup>2</sup>           |
| BMI units                                 | KG/M2                                |
| Temperature ( <i>xxx.x</i> )              | ND - Not Done                        |
| Route of measurement                      | Oral <input type="radio"/>           |
|   | Axillary <input type="radio"/>       |
|   | Other <input type="radio"/>          |
| If Other, specify                         |                                      |
| Pulse ( <i>xxx</i> )                      | ND - Not Done                        |
| Pulse units                               | BPM                                  |
| Respiratory Rate ( <i>xxx</i> )           | ND - Not Done                        |
| Respiratory Rate units                    | BREATHS/MIN                          |
| Systolic Blood Pressure ( <i>xxx</i> )    | ND - Not Done                        |
| Systolic Blood Pressure units             | MMHG                                 |
| Diastolic Blood Pressure ( <i>xxx</i> )   | ND - Not Done                        |
| Diastolic Blood Pressure units            | MMHG                                 |
| Height (derived)                          |                                      |
| Weight (derived)                          |                                      |

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 21:30:05

Generated On: 10 Jun 2021 09:13:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 OCT 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) 05 Apr 2021 21:30:05

Generated On: 10 Jun 2021 09:13:32

Date of assessment (dd MMM yyyy) 2 OCT 2020

Is the participant of childbearing potential? Yes ☒  
No ☐

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

If Partner medically sterile or Other, specify \_\_\_\_\_  
If Surgically sterile, date of surgery (dd MMM yyyy) \_\_\_\_\_  
Date of surgery unknown False  
If Post-menopausal, date of last menstruation (dd MMM yyyy) \_\_\_\_\_  
Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 05 Apr 2021 21:30:05

Generated On: 10 Jun 2021 09:13:32

|                                     |   |
|-------------------------------------|---|
| Was the pregnancy test performed?   | Yes <input checked="" type="radio"/>      |
|                                     | No <input type="radio"/>                  |
| Date of test ( <i>dd MMM yyyy</i> ) | 2 OCT 2020                                |
| Test performed                      | Urine <input checked="" type="radio"/>    |
|                                     | Serum <input type="radio"/>               |
| Result                              | Positive <input type="radio"/>            |
|                                     | Negative <input checked="" type="radio"/> |
| Was FSH sample collected?           | Yes <input type="radio"/>                 |
|                                     | No <input checked="" type="radio"/>       |
| Collection date                     |   |
| Collection time                     |   |
| Collection date and time (derived)  |   |

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Apr 2021 21:30:05

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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**

**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) 05 Apr 2021 21:30:05

Generated On: 10 Jun 2021 09:13:32

|  |       |
|--|-------|
| <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) 05 Apr 2021 21:30:06

Generated On: 10 Jun 2021 09:13:32

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 2 OCT 2020                              |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | VISIT1                                  |

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 05 Apr 2021 21:30:06

Generated On: 10 Jun 2021 09:13:32

What was the date of randomization? (dd MMM yyyy) 02 OCT 2020

What was the participant's randomization number? 116294

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Apr 2021 21:30:06

Generated On: 10 Jun 2021 09:13:32

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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Apr 2021 21:30:06

Generated On: 10 Jun 2021 09:13:32

|                                     |  |
|-------------------------------------|--|
| 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)    | 2 OCT 2020   |
| Time of assessment (00:00-23:59)    | 13:16 (24 HR)  |
| Vital Signs Date and Time (derived) | 2 OCT 2020 13:16   |
| Temperature (xxx.x)                 | 97.8 F   |
| Route of measurement                | Oral <input type="radio"/><br>Axillary <input type="radio"/><br>Other <input checked="" type="radio"/> |
| If Other, specify                   | TEMPORAL/FOREHEAD<br>SCANNER USED  |
| Pulse (xxx)                         | 86 beats/min   |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 18 breaths/min   |
| Respiratory Rate units              | BREATHS/MIN  |
| Systolic Blood Pressure (xxx)       | 139 mmHg   |
| Systolic Blood Pressure units       | MMHG   |
| Diastolic Blood Pressure (xxx)      | 88 mmHg  |
| Diastolic Blood Pressure units      | MMHG   |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 21:30:06

Generated On: 10 Jun 2021 09:13:32

|                                     |  |
|-------------------------------------|--|
| 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)    | 2 OCT 2020   |
| Time of assessment (00:00-23:59)    | 16:02 (24 HR)  |
| Vital Signs Date and Time (derived) | 2 OCT 2020 16:02   |
| Temperature (xxx.x)                 | 97.6 F   |
| Route of measurement                | Oral <input type="radio"/><br>Axillary <input type="radio"/><br>Other <input checked="" type="radio"/> |
| If Other, specify                   | TEMPORAL/FOREHEAD<br>SCANNER USED  |
| Pulse (xxx)                         | 80 beats/min   |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 18 breaths/min   |
| Respiratory Rate units              | BREATHS/MIN  |
| Systolic Blood Pressure (xxx)       | 143 mmHg   |
| Systolic Blood Pressure units       | MMHG   |
| Diastolic Blood Pressure (xxx)      | 68 mmHg  |
| Diastolic Blood Pressure units      | MMHG   |

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 21:30:06

Generated On: 10 Jun 2021 09:13:32

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 05 Apr 2021 21:30:06

Generated On: 10 Jun 2021 09:13:32

Was the pregnancy test performed? Yes ☐  
No ☒

Date of test (dd MMM yyyy) \_\_\_\_\_

Test performed Urine ☐  
Serum ☐

Result Positive ☐  
Negative ☐

Was FSH sample collected? Yes ☐  
No ☒

Collection date \_\_\_\_\_

Collection time \_\_\_\_\_

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 05 Apr 2021 21:30:06

Generated On: 10 Jun 2021 09:13:32

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 2 OCT 2020

What was the treatment time? (00:00-23:59) 15:32 (24 HR)

Treatment Date and Time (derived) 2 OCT 2020 15:32

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 21:30:06

Generated On: 10 Jun 2021 09:13:32

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 2 OCT 2020                           |
| Collection time (00:00-23:59)      | 13:16 (24 HR)                        |
| Collection date and time (derived) | 2 OCT 2020 13:16                     |

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Apr 2021 21:30:05

Generated On: 10 Jun 2021 09:13:32

|                               |                           |                                 |                                    |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) |                           |                                 | 2 OCT 2020                         |
| Lab Test                      | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1         | Yes                       | 13:43                           | 2 OCT 2020 13:43                   |
| Nasopharyngeal Swab 2         | No                        |                                 |                                    |



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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:30:06

Generated On: 10 Jun 2021 09:13:32

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: 10 Jun 2021 09:13:32

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 16:11

PC Open Date & Time

02 OCT 2020 15:52

PC Close Date & Time

02 OCT 2020 18:22

US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.7 °F

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

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

|                      |                   |
|----------------------|-------------------|
| PC Time Stamp        | 02 OCT 2020 20:46 |
| PC Open Date & Time  | 02 OCT 2020 19:17 |
| PC Close Date & Time | 03 OCT 2020 11:59 |

US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 19:16

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 OCT 2020 12:33

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.2 °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

05 OCT 2020 18:23

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

|  |                                      |
|--|--------------------------------------|
| Was <b>TEMPERATURE</b> taken?                            | Yes <input checked="" type="radio"/> |
|  | No <input type="radio"/>             |
| Please record your <b>TEMPERATURE</b> in °F              | 99.1 °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        | 06 OCT 2020 18:26 |
| PC Open Date & Time  | 06 OCT 2020 12:00 |
| PC Close Date & Time | 07 OCT 2020 11:59 |

US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 OCT 2020 14:34

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59



US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

|  |                                      |
|--|--------------------------------------|
| Was <b>TEMPERATURE</b> taken?                            | Yes <input checked="" type="radio"/> |
|  | No <input type="radio"/>             |
| Please record your <b>TEMPERATURE</b> in °F              | 98.5 °F                              |
| Was any <b>MEDICATION TAKEN</b> today for pain or fever? | Yes <input 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        | 08 OCT 2020 19:51 |
| PC Open Date & Time  | 08 OCT 2020 12:00 |
| PC Close Date & Time | 09 OCT 2020 11:59 |

US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 8

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

09 OCT 2020 20:53

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 9

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 10

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

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

11 OCT 2020 13:42

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3602123

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 16:12

PC Open Date & Time

02 OCT 2020 15:52

PC Close Date & Time

02 OCT 2020 18:22

US3602123

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 20:46

PC Open Date & Time

02 OCT 2020 19:17

PC Close Date & Time

03 OCT 2020 11:59

US3602123

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

03 OCT 2020 19:16

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3602123

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:32

**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

04 OCT 2020 12:32

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59



US3602123

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

05 OCT 2020 18:24

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3602123

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:32

**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

06 OCT 2020 18:27

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3602123

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

07 OCT 2020 14:34

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3602123

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

08 OCT 2020 19:51

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3602123

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3602123

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:32

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 02 OCT 2020 16:13 |
| PC Open Date & Time  | 02 OCT 2020 15:52 |
| PC Close Date & Time | 02 OCT 2020 18:22 |

US3602123

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

- None ☐
- No interference with activity ☒
- Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐
- Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

- None ☐
- No interference with activity ☒
- Some interference with activity ☐
- Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

- None ☒
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

- None ☒
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

- None ☐
- No interference with activity or  
1-2 episodes/24 hours ☒
- Some interference with activity  
or >2 episodes/24 hours ☐
- Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

- None ☒
- No interference with activity ☐
- Some interference with activity  
not requiring medical attention ☐
- Prevents daily activity and  
requires medical attention ☐

US3602123

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:32

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 02 OCT 2020 20:47 |
| PC Open Date & Time  | 02 OCT 2020 19:17 |
| PC Close Date & Time | 03 OCT 2020 11:59 |



US3602123

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3602123

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:32

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 03 OCT 2020 19:16 |
| PC Open Date & Time          | 03 OCT 2020 12:00 |
| PC Close Date & Time         | 04 OCT 2020 11:59 |

US3602123

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:32**

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 04 OCT 2020 12:32 |
| PC Open Date & Time          | 04 OCT 2020 12:00 |
| PC Close Date & Time         | 05 OCT 2020 11:59 |

US3602123

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3602123

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:32

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 05 OCT 2020 18:24 |
| PC Open Date & Time          | 05 OCT 2020 12:00 |
| PC Close Date & Time         | 06 OCT 2020 11:59 |

US3602123

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:32

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☒

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:32

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 06 OCT 2020 18:27 |
| PC Open Date & Time          | 06 OCT 2020 12:00 |
| PC Close Date & Time         | 07 OCT 2020 11:59 |



US3602123

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:32

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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US3602123

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:32

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 07 OCT 2020 14:35 |
| PC Open Date & Time          | 07 OCT 2020 12:00 |
| PC Close Date & Time         | 08 OCT 2020 11:59 |

US3602123

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:13:32

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3602123

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:13:32

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 08 OCT 2020 19:52 |
| PC Open Date & Time          | 08 OCT 2020 12:00 |
| PC Close Date & Time         | 09 OCT 2020 11:59 |

US3602123

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

**HEADACHE**

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp 09 OCT 2020 20:53

PC Open Date & Time 09 OCT 2020 12:00

PC Close Date & Time 10 OCT 2020 11:59

US3602123

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your

None ☐

**HEADACHE**

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3602123

Folder: Diary Dose 1 (1)

Form: Headache\_Day(10)

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 10

Select one response below to indicate the intensity of your

None ☒

**HEADACHE**

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 OCT 2020 13:42

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3602123

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:13:32

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | DAY 8  |
| Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| PC Time stamp   | 09 OCT 2020 20:53  |
| PC Open Date & Time   | 09 OCT 2020 12:00  |
| PC Close Date & Time  | 10 OCT 2020 11:59  |



US3602123

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 09:13:32

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

US3602123

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 09:13:32

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | DAY 10   |
| Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| PC Time stamp   | 11 OCT 2020 13:42  |
| PC Open Date & Time   | 11 OCT 2020 12:00  |
| PC Close Date & Time  | 12 OCT 2020 11:59  |

US3602123

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:30:05

Generated On: 10 Jun 2021 09:13:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3602123

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:30:05

Generated On: 10 Jun 2021 09:13:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602123

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:30:05

Generated On: 10 Jun 2021 09:13:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3602123

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:30:05

Generated On: 10 Jun 2021 09:13:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602123

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:30:05

Generated On: 10 Jun 2021 09:13:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3602123

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:30:05

Generated On: 10 Jun 2021 09:13:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3602123

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 21:30:06

Generated On: 10 Jun 2021 09:13:32

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

|                          |             |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 27 OCT 2020 |
|--------------------------|-------------|

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

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

US3602123

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Apr 2021 21:30:06

Generated On: 10 Jun 2021 09:13:32

|                                     |   |
|-------------------------------------|---|
| Timepoint                           | Pre-Dose <input checked="" type="radio"/> |
|                                     | Post-Dose <input type="radio"/>           |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>      |
|                                     | No <input type="radio"/>                  |
| Date of assessment (dd MMM yyyy)    | 27 OCT 2020                               |
| Time of assessment (00:00-23:59)    | 08:36 (24 HR)                             |
| Vital Signs Date and Time (derived) | 27 OCT 2020 08:36                         |
| Temperature (xxx.x)                 | 97.8 F                                    |
| Route of measurement                | Oral <input type="radio"/>                |
|                                     | Axillary <input type="radio"/>            |
|                                     | Other <input checked="" type="radio"/>    |
| If Other, specify                   | TEMPORAL/FOREHEAD<br>SCANNER WAS USED     |
| Pulse (xxx)                         | 76 beats/min                              |
| Pulse units                         | BPM                                       |
| Respiratory Rate (xxx)              | 18 breaths/min                            |
| Respiratory Rate units              | BREATHS/MIN                               |
| Systolic Blood Pressure (xxx)       | 123 mmHg                                  |
| Systolic Blood Pressure units       | MMHG                                      |
| Diastolic Blood Pressure (xxx)      | 78 mmHg                                   |
| Diastolic Blood Pressure units      | MMHG                                      |

US3602123

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 21:30:06

Generated On: 10 Jun 2021 09:13:32

|                                     |  |
|-------------------------------------|--|
| Timepoint                           | Pre-Dose <input type="radio"/>             |
|                                     | Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>       |
|                                     | No <input type="radio"/>                   |
| Date of assessment (dd MMM yyyy)    | 27 OCT 2020                                |
| Time of assessment (00:00-23:59)    | 10:44 (24 HR)                              |
| Vital Signs Date and Time (derived) | 27 OCT 2020 10:44                          |
| Temperature (xxx.x)                 | 97.6 F                                     |
| Route of measurement                | Oral <input type="radio"/>                 |
|                                     | Axillary <input type="radio"/>             |
|                                     | Other <input checked="" type="radio"/>     |
| If Other, specify                   | TEMPORAL/FOREHEAD<br>SCANNER WAS USED      |
| Pulse (xxx)                         | 75 beats/min                               |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 18 breaths/min                             |
| Respiratory Rate units              | BREATHS/MIN                                |
| Systolic Blood Pressure (xxx)       | 135 mmHg                                   |
| Systolic Blood Pressure units       | MMHG                                       |
| Diastolic Blood Pressure (xxx)      | 83 mmHg                                    |
| Diastolic Blood Pressure units      | MMHG                                       |

US3602123

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 21:30:06

Generated On: 10 Jun 2021 09:13:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 OCT 2020

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

US3602123

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 05 Apr 2021 21:30:06

Generated On: 10 Jun 2021 09:13:32

Was the pregnancy test performed? Yes ☒  
No ☐

Date of test (dd MMM yyyy) 27 OCT 2020

Test performed Urine ☒  
Serum ☐

Result Positive ☐  
Negative ☒

Was FSH sample collected? Yes ☐  
No ☒

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

US3602123

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 05 Apr 2021 21:30:06

Generated On: 10 Jun 2021 09:13:32

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 27 OCT 2020

What was the treatment time? (00:00-23:59) 10:14 (24 HR)

Treatment Date and Time (derived) 27 OCT 2020 10:14

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

US3602123

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 21:30:06

Generated On: 10 Jun 2021 09:13:32

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

27 OCT 2020

Collection time (00:00-23:59)

08:36 (24 HR)

Collection date and time (derived)

27 OCT 2020 08:36

US3602123

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Apr 2021 21:30:06

Generated On: 10 Jun 2021 09:13:32

|                               |                           |                                 |                                    |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) |                           |                                 | 27 OCT 2020                        |
| Lab Test                      | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1         | Yes                       | 08:45                           | 27 OCT 2020 08:45                  |
| Nasopharyngeal Swab 2         | No                        |                                 |                                    |



US3602123

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:30:06

Generated On: 10 Jun 2021 09:13:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602123

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 OCT 2020 11:03

PC Open Date & Time

27 OCT 2020 10:34

PC Close Date & Time

27 OCT 2020 13:04

US3602123

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.0 °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        | 28 OCT 2020 05:58 |
| PC Open Date & Time  | 27 OCT 2020 13:59 |
| PC Close Date & Time | 28 OCT 2020 11:59 |

US3602123

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **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

28 OCT 2020 14:44

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3602123

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **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

29 OCT 2020 20:03

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59

US3602123

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

31 OCT 2020 08:54

PC Open Date & Time

30 OCT 2020 12:00

PC Close Date & Time

31 OCT 2020 11:59

US3602123

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 NOV 2020 06:10

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3602123

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **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

01 NOV 2020 15:59

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59



US3602123

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 NOV 2020 18:13

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3602123

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

27 OCT 2020 11:03

PC Open Date & Time

27 OCT 2020 10:34

PC Close Date & Time

27 OCT 2020 13:04

US3602123

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

28 OCT 2020 05:58

PC Open Date & Time

27 OCT 2020 13:59

PC Close Date & Time

28 OCT 2020 11:59

US3602123

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:32

**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

28 OCT 2020 14:44

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3602123

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:32

**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

29 OCT 2020 20:03

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59

US3602123

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

31 OCT 2020 08:54

PC Open Date & Time

30 OCT 2020 12:00

PC Close Date & Time

31 OCT 2020 11:59

US3602123

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:32

**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

01 NOV 2020 06:10

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3602123

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:32

**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

01 NOV 2020 16:00

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59



US3602123

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:32

**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

02 NOV 2020 18:13

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3602123

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3602123

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:32

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 27 OCT 2020 11:04 |
| PC Open Date & Time  | 27 OCT 2020 10:34 |
| PC Close Date & Time | 27 OCT 2020 13:04 |

US3602123

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

- None ☐
- No interference with activity ☒
- Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐
- Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

- None ☐
- No interference with activity ☒
- Some interference with activity ☐
- Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

- None ☒
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

- None ☒
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

- None ☒
- No interference with activity or  
1-2 episodes/24 hours ☐
- Some interference with activity  
or >2 episodes/24 hours ☐
- Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

- None ☒
- No interference with activity ☐
- Some interference with activity  
not requiring medical attention ☐
- Prevents daily activity and  
requires medical attention ☐

US3602123

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:32

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 28 OCT 2020 05:59 |
| PC Open Date & Time  | 27 OCT 2020 13:59 |
| PC Close Date & Time | 28 OCT 2020 11:59 |

US3602123

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3602123

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:32

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 28 OCT 2020 14:45 |
| PC Open Date & Time          | 28 OCT 2020 12:00 |
| PC Close Date & Time         | 29 OCT 2020 11:59 |

US3602123

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:32

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)



US3602123

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:32

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 29 OCT 2020 20:03 |
| PC Open Date & Time          | 29 OCT 2020 12:00 |
| PC Close Date & Time         | 30 OCT 2020 11:59 |

US3602123

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3602123

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:32

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 31 OCT 2020 08:54 |
| PC Open Date & Time          | 30 OCT 2020 12:00 |
| PC Close Date & Time         | 31 OCT 2020 11:59 |

US3602123

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:32

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:32

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 01 NOV 2020 06:10 |
| PC Open Date & Time          | 31 OCT 2020 12:00 |
| PC Close Date & Time         | 01 NOV 2020 11:59 |

US3602123

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:32

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

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**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:32**

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

US3602123

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:32**

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 02 NOV 2020 18:13 |
| PC Open Date & Time          | 02 NOV 2020 12:00 |
| PC Close Date & Time         | 03 NOV 2020 11:59 |

US3602123

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:30:05

Generated On: 10 Jun 2021 09:13:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3602123

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:30:05

Generated On: 10 Jun 2021 09:13:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602123

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:30:05

Generated On: 10 Jun 2021 09:13:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3602123

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:30:05

Generated On: 10 Jun 2021 09:13:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602123

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:30:05

Generated On: 10 Jun 2021 09:13:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3602123

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:30:05

Generated On: 10 Jun 2021 09:13:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602123

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 21:30:06

Generated On: 10 Jun 2021 09:13:32

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 24 NOV 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | VISIT3                                  |



US3602123

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 21:30:06

Generated On: 10 Jun 2021 09:13:32

|                                     |  |
|-------------------------------------|--|
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>   |
|                                     | No <input type="radio"/>               |
| Date of assessment (dd MMM yyyy)    | 24 NOV 2020                            |
| Time of assessment (00:00-23:59)    | 08:30 (24 HR)                          |
| Vital Signs Date and Time (derived) | 24 NOV 2020 08:30                      |
| Temperature (xxx.x)                 | 97.3 F                                 |
| Route of measurement                | Oral <input type="radio"/>             |
|                                     | Axillary <input type="radio"/>         |
|                                     | Other <input checked="" type="radio"/> |
| If Other, specify                   | TEMPORAL/FOREHEAD<br>SCANNER WAS USED  |
| Pulse (xxx)                         | 79 beats/min                           |
| Pulse units                         | BPM                                    |
| Respiratory Rate (xxx)              | 16 breaths/min                         |
| Respiratory Rate units              | BREATHS/MIN                            |
| Systolic Blood Pressure (xxx)       | 136 mmHg                               |
| Systolic Blood Pressure units       | MMHG                                   |
| Diastolic Blood Pressure (xxx)      | 79 mmHg                                |
| Diastolic Blood Pressure units      | MMHG                                   |
| Height (derived)                    |  |
| Weight (derived)                    |  |

US3602123

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 21:30:06

Generated On: 10 Jun 2021 09:13:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 NOV 2020

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

US3602123

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 21:30:06

Generated On: 10 Jun 2021 09:13:32

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 24 NOV 2020                          |
| Collection time (00:00-23:59)      | 08:30 (24 HR)                        |
| Collection date and time (derived) | 24 NOV 2020 08:30                    |

US3602123

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:30:06

Generated On: 10 Jun 2021 09:13:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| TIMEPOINT   | DAY 61   |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Date and time of submission   | 01 DEC 2020 08:29:29   |
| Patient Cloud Open Date & Time  | 29 NOV 2020 00:01  |
| Patient Cloud Close Date & Time   | 03 DEC 2020 23:59  |

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| TIMEPOINT   | DAY 68   |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input 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   | 08 DEC 2020 18:29:29   |
| Patient Cloud Open Date & Time  | 06 DEC 2020 00:01  |
| Patient Cloud Close Date & Time   | 10 DEC 2020 23:59  |

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| TIMEPOINT   | DAY 75  |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input 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"/>   |

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>  | 13 DEC 2020 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 17 DEC 2020 23:59 |



US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 82

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 DEC 2020 11:52:26

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 DEC 2020 12:00:30

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| TIMEPOINT   | DAY 96   |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Date and time of submission   | 05 JAN 2021 12:19:11   |
| Patient Cloud Open Date & Time  | 03 JAN 2021 00:01  |
| Patient Cloud Close Date & Time   | 07 JAN 2021 23:59  |

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 103

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

No ☒

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 JAN 2021 16:33:40

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 110

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

No ☒

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 17:59:49

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 JAN 2021 17:39:08

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 FEB 2021 10:19:55

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| 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 checked="" type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/>   |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input checked="" type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><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"/> |
| Date and time of submission   | 09 FEB 2021 12:28:34   |
| Patient Cloud Open Date & Time  | 07 FEB 2021 00:01  |
| Patient Cloud Close Date & Time   | 11 FEB 2021 23:59  |



US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 FEB 2021 18:00:52

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**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 ☒

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 FEB 2021 11:26:35

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

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

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

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[Patient Cloud Close Date & Time](#)

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04 MAR 2021 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**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 MAR 2021 10:03:25

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 MAR 2021 06:32:00

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**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

21 MAR 2021 09:25:18

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**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

30 MAR 2021 12:15:50

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59



US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**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 APR 2021 13:34:28

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 APR 2021 12:01:01

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 APR 2021 17:59:30

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 APR 2021 12:00:10

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**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

03 MAY 2021 08:54:44

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 222

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

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[Patient Cloud Close Date & Time](#)

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13 MAY 2021 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| TIMEPOINT   | DAY 229   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input 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"/>   |



**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

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[Patient Cloud Close Date & Time](#)

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20 MAY 2021 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| TIMEPOINT   | DAY 236   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><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"/>   |

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

23 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 243

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

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[Patient Cloud Close Date & Time](#)

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03 JUN 2021 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| TIMEPOINT   | DAY 250  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><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"/>  |

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

13 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| TIMEPOINT   | DAY 264  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><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"/>  |

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>  | 20 JUN 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 24 JUN 2021 23:59 |

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| TIMEPOINT   | DAY 271  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="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"/>  |

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

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[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**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 ☐

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| 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"/>   |



**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 15 JUL 2021 23:59 |

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| TIMEPOINT   | DAY 292  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><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"/>  |

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

18 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| 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="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"/>  |

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| 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"/>  |

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**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°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 ☐



**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

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[Patient Cloud Close Date & Time](#)

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12 AUG 2021 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| 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"/>   |

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2021 00:01 |
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|   |                   |
|---|-------------------|
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 19 AUG 2021 23:59 |
|---|-------------------|

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

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

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

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

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[Patient Cloud Close Date & Time](#)

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26 AUG 2021 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| 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"/>  |

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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29 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 SEP 2021 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| 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"/>  |



**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

05 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| 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="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"/>   |

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

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[Patient Cloud Close Date & Time](#)

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23 SEP 2021 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| TIMEPOINT   | DAY 362  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><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"/>  |

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

03 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

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

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

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**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 ☐

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| 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="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"/>  |

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>  | 24 OCT 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 28 OCT 2021 23:59 |

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**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 ☐



**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| 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"/>  |

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| 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"/>   |

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

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[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| 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"/>   |

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

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[Patient Cloud Close Date & Time](#)

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25 NOV 2021 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 425

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

Fever (Temperature  $\geq$  100.4°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 ☐



**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

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[Patient Cloud Close Date & Time](#)

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02 DEC 2021 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

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

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

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| 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"/>   |

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

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[Patient Cloud Close Date & Time](#)

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16 DEC 2021 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| 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"/>   |

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>  | 19 DEC 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 23 DEC 2021 23:59 |

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

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

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



**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| TIMEPOINT   | DAY 460   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><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"/>   |

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

02 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| 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"/>   |

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**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 ☐

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

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[Patient Cloud Close Date & Time](#)

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20 JAN 2022 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 488

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

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

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

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

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

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

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

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

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**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 ☐ 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 ☐

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

06 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

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

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

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

13 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**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 ☐



**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>  | 20 FEB 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 24 FEB 2022 23:59 |

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| 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"/>  |

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

|   |  |
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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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27 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 MAR 2022 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**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 ☐

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

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[Patient Cloud Close Date & Time](#)

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10 MAR 2022 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| 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"/>   |

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**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 ☐



**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

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[Patient Cloud Close Date & Time](#)

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24 MAR 2022 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| 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"/>  |

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

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[Patient Cloud Close Date & Time](#)

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31 MAR 2022 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**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 ☐

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

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[Patient Cloud Close Date & Time](#)

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07 APR 2022 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**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 ☐

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

10 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**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 ☐



**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

17 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**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 ☐

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>  | 24 APR 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 28 APR 2022 23:59 |

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**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 ☐

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

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

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

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

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[Patient Cloud Close Date & Time](#)

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12 MAY 2022 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**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 ☐



**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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15 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2022 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| TIMEPOINT   | DAY 600  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><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"/>  |

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

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[Patient Cloud Close Date & Time](#)

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26 MAY 2022 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| TIMEPOINT   | DAY 607  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><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"/>  |

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| 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"/>   |

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

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[Patient Cloud Close Date & Time](#)

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09 JUN 2022 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| TIMEPOINT   | DAY 621  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><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"/>  |



**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

12 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| TIMEPOINT   | DAY 628   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="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"/>   |

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| 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"/>   |

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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26 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 JUN 2022 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| 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"/>   |

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

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[Patient Cloud Close Date & Time](#)

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07 JUL 2022 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| TIMEPOINT   | DAY 649   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="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"/>   |



**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>  | 10 JUL 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 14 JUL 2022 23:59 |

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**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 ☐

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| 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"/>   |

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

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[Patient Cloud Close Date & Time](#)

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04 AUG 2022 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

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

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



**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

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[Patient Cloud Close Date & Time](#)

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11 AUG 2022 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| 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="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"/>   |

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>  | 14 AUG 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 18 AUG 2022 23:59 |

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| 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"/>  |

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

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[Patient Cloud Close Date & Time](#)

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25 AUG 2022 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| TIMEPOINT   | DAY 698  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><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"/>  |

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

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

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

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| TIMEPOINT   | DAY 719  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><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"/>  |

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

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[Patient Cloud Close Date & Time](#)

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22 SEP 2022 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| TIMEPOINT   | DAY 726   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><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"/>   |

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2022 00:01 |
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|   |                   |
|---|-------------------|
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 29 SEP 2022 23:59 |
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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| 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 <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"/>   |



**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

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[Patient Cloud Close Date & Time](#)

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06 OCT 2022 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| 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"/>   |

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>  | 09 OCT 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 13 OCT 2022 23:59 |

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| 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"/>   |

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>  | 16 OCT 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 20 OCT 2022 23:59 |

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**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 ☐

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>  | 23 OCT 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 27 OCT 2022 23:59 |

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| 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"/>   |



**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

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[Patient Cloud Close Date & Time](#)

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03 NOV 2022 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| TIMEPOINT   | DAY 768   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="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"/>   |

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

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[Patient Cloud Close Date & Time](#)

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10 NOV 2022 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

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

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

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>  | 13 NOV 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 17 NOV 2022 23:59 |

US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**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 ☐

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

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[Patient Cloud Close Date & Time](#)

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24 NOV 2022 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

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[Patient Cloud Close Date & Time](#)

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01 DEC 2022 23:59

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US3602123

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:13:32

| 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"/>   |

**US3602123**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

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

[Patient Cloud Close Date & Time](#)

08 DEC 2022 23:59

**US3602123**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 10 Jun 2021 09:13:32**

| Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other? | Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache? | Date & Time of Submission |
|---|--|---------------------------|
| No  |  | 05 MAR 2021 15:05:51      |

US3602123

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:30:05

Generated On: 10 Jun 2021 09:13:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3602123

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:30:05

Generated On: 10 Jun 2021 09:13:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602123

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:30:05

Generated On: 10 Jun 2021 09:13:32

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

MISSED SC DUE TO LACK OF  
CLARITY CONCERNING EUA  
PROTOCOL FOR COMBINING  
PART A + B SC.  
UNDERSTANDING WAS PART A  
SC RESUME AFTER PART B.  
FOLLOWING CLARIFICATION,  
SC SCHEDULE CHANGES  
IMPLEMENTED.

US3602123

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:30:05

Generated On: 10 Jun 2021 09:13:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3602123

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:30:05

Generated On: 10 Jun 2021 09:13:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3602123

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:30:05

Generated On: 10 Jun 2021 09:13:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602123

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:30:05

Generated On: 10 Jun 2021 09:13:32

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*

US3602123

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:30:05

Generated On: 10 Jun 2021 09:13:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602123

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 May 2021 01:32:35

Generated On: 10 Jun 2021 09:13:32

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

|                          |             |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 26 APR 2021 |
|--------------------------|-------------|

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

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

US3602123

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 May 2021 01:32:35

Generated On: 10 Jun 2021 09:13:32

|                                     |  |
|-------------------------------------|--|
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>   |
|                                     | No <input type="radio"/>               |
| Date of assessment (dd MMM yyyy)    | 26 APR 2021                            |
| Time of assessment (00:00-23:59)    | 08:20 (24 HR)                          |
| Vital Signs Date and Time (derived) | 26 APR 2021 08:20                      |
| Temperature (xxx.x)                 | 96.2 F                                 |
| Route of measurement                | Oral <input type="radio"/>             |
|                                     | Axillary <input type="radio"/>         |
|                                     | Other <input checked="" type="radio"/> |
| If Other, specify                   | TEMPORAL/FOREHEAD<br>SCANNER WAS USED  |
| Pulse (xxx)                         | 74 beats/min                           |
| Pulse units                         | BPM                                    |
| Respiratory Rate (xxx)              | 20 breaths/min                         |
| Respiratory Rate units              | BREATHS/MIN                            |
| Systolic Blood Pressure (xxx)       | 126 mmHg                               |
| Systolic Blood Pressure units       | MMHG                                   |
| Diastolic Blood Pressure (xxx)      | 87 mmHg                                |
| Diastolic Blood Pressure units      | MMHG                                   |
| Height (derived)                    |  |
| Weight (derived)                    |  |

US3602123

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 May 2021 01:32:35

Generated On: 10 Jun 2021 09:13:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 APR 2021

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

US3602123

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 May 2021 01:32:35

Generated On: 10 Jun 2021 09:13:32

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 APR 2021

Collection time (00:00-23:59)

08:30 (24 HR)

Collection date and time (derived)

26 APR 2021 08:30



US3602123

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 May 2021 01:32:35

Generated On: 10 Jun 2021 09:13:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3602123**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

**US3602123**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:32**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**US3602123**

**Folder: Covid-19 Assessment (1)**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:13:32**

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

**US3602123**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 10 Jun 2021 09:13:32**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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**US3602123**

**Folder: Illness Visit (1)**

**Form: Saliva Collection**

**Generated On: 10 Jun 2021 09:13:32**

| Visit  | Was Saliva Collected? | Date of Collection |
|--------|-----------------------|--------------------|
| Day 3  |                       |                    |
| Day 5  |                       |                    |
| Day 7  |                       |                    |
| Day 9  |                       |                    |
| Day 14 |                       |                    |
| Day 21 |                       |                    |
| Day 28 |                       |                    |

**US3602123**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:32**

Was this visit performed? Yes ☐  
No ☐

Visit date (dd MMM yyyy) \_\_\_\_\_

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

Folder OID \_\_\_\_\_

US3602123

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:32

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



US3602123

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:13:32

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

**US3602123**

**Folder: Illness Visit Day 1 (1)**

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

**Generated On: 10 Jun 2021 09:13:32**

|  |                        |                          |
|--|------------------------|--------------------------|
| Was Blood Sample Taken for Immunologic Assessment of | Yes                    | <input type="checkbox"/> |
| SARS_COV-2 Infection?                                | No                     | <input type="checkbox"/> |
|  | NA (COVID-19 Negative) | <input type="checkbox"/> |

|                    |  |
|--------------------|--|
| Date of Collection |  |
|--------------------|--|

**US3602123**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:32**

Was this visit performed? Yes ☐  
No ☐

Visit date (dd MMM yyyy) \_\_\_\_\_

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

Folder OID \_\_\_\_\_

US3602123

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:32

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

US3602123

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:13:32

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

**US3602123**

**Folder: Convalescence Visit Day 28 (1)**

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

**Generated On: 10 Jun 2021 09:13:32**

|  |   |
|--|---|
| Was Blood Sample Taken for Immunologic Assessment of | Yes <input type="checkbox"/>                    |
| SARS_COV-2 Infection?                                | No <input type="checkbox"/>                     |
|  | NA (COVID-19 Negative) <input type="checkbox"/> |

|                    |  |
|--------------------|--|
| Date of Collection |  |
|--------------------|--|

US3602123

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

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 21:30:04

Generated On: 10 Jun 2021 09:13:32

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

|                          |             |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 12 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 |
|------------|---------------|

US3602123

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

Form: Unblinding

Data signed: (b) (4) 05 Apr 2021 21:30:04

Generated On: 10 Jun 2021 09:13:32

|   |   |
|---|---|
| Date of updated informed consent ( <i>dd MMM yyyy</i> )               | 12 JAN 2021   |
| N/A - Subject Unblinded under Amendment 5 and Discontinued from Study | False   |
| Was the participant unblinded?  | Yes <input checked="" type="radio"/><br>No <input type="radio"/>  |
| Under what version of the Protocol was the Participant unblinded?     | Amendment 5 <input type="radio"/><br>Amendment 6 or later <input checked="" type="radio"/>                            |
| Date of unblinding ( <i>dd MMM yyyy</i> )                             | 12 JAN 2021   |
| Participant randomization assignment                                  | mRNA-1273 <input type="radio"/><br>Placebo <input checked="" type="radio"/>   |
| Actual Dose 1   | mRNA-1273 <input type="radio"/><br>Placebo <input checked="" type="radio"/><br>Not Administered <input type="radio"/> |
| Actual Dose 2   | mRNA-1273 <input type="radio"/><br>Placebo <input checked="" type="radio"/><br>Not Administered <input type="radio"/> |
| Will participant receive mRNA-1273?                                   | Yes <input checked="" type="radio"/><br>No <input type="radio"/>  |
| Placebo Only Flag   | 1   |
| Continuing with mRNA-1273   | 1   |



US3602123

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Apr 2021 21:30:04

Generated On: 10 Jun 2021 09:13:32

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

US3602123

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Apr 2021 21:30:04

Generated On: 10 Jun 2021 09:13:32

|                                     |  |
|-------------------------------------|--|
| Height                              | ND - Not Done  |
| Weight                              | ND - Not Done  |
| BMI (xxx.x)                         |  |
| 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)    | 12 JAN 2021  |
| Time of assessment (00:00-23:59)    | 14:00 (24 HR)  |
| Vital Signs Date and Time (derived) | 12 JAN 2021 14:00  |
| Temperature (xxx.x)                 | 97.2 F   |
| Route of measurement                | Oral <input type="radio"/><br>Axillary <input type="radio"/><br>Other <input checked="" type="radio"/> |
| If Other, specify                   | TEMPORAL/FOREHEAD<br>SCANNER WAS USED  |
| Pulse (xxx)                         | 83 beats/min   |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 16 breaths/min   |
| Respiratory Rate units              | BREATHS/MIN  |
| Systolic Blood Pressure (xxx)       | 131 mmHg   |
| Systolic Blood Pressure units       | MMHG   |
| Diastolic Blood Pressure (xxx)      | 85 mmHg  |
| Diastolic Blood Pressure units      | MMHG   |

US3602123

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 21:30:04

Generated On: 10 Jun 2021 09:13:32

|                                     |  |
|-------------------------------------|--|
| Height                              | ND - Not Done  |
| Weight                              | ND - Not Done  |
| BMI (xxx.x)                         |  |
| 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)    | 12 JAN 2021  |
| Time of assessment (00:00-23:59)    | 16:55 (24 HR)  |
| Vital Signs Date and Time (derived) | 12 JAN 2021 16:55  |
| Temperature (xxx.x)                 | 97.6 F   |
| Route of measurement                | Oral <input type="radio"/><br>Axillary <input type="radio"/><br>Other <input checked="" type="radio"/> |
| If Other, specify                   | TEMPORAL/FOREHEAD<br>SCANNER WAS USED  |
| Pulse (xxx)                         | 83 beats/min   |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 16 breaths/min   |
| Respiratory Rate units              | BREATHS/MIN  |
| Systolic Blood Pressure (xxx)       | 134 mmHg   |
| Systolic Blood Pressure units       | MMHG   |
| Diastolic Blood Pressure (xxx)      | 77 mmHg  |
| Diastolic Blood Pressure units      | MMHG   |

US3602123

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

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 21:30:03

Generated On: 10 Jun 2021 09:13:32

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

12 JAN 2021

---

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

---

US3602123

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

Form: Pregnancy Test

Data signed: (b) (4) 05 Apr 2021 21:30:03

Generated On: 10 Jun 2021 09:13:32

|                                     |   |
|-------------------------------------|---|
| Was the pregnancy test performed?   | Yes <input checked="" type="radio"/>      |
|                                     | No <input type="radio"/>                  |
| Date of test ( <i>dd MMM yyyy</i> ) | 12 JAN 2021                               |
| Test performed                      | Urine <input checked="" type="radio"/>    |
|                                     | Serum <input type="radio"/>               |
| Result                              | Positive <input type="radio"/>            |
|                                     | Negative <input checked="" type="radio"/> |
| Was FSH sample collected?           | Yes <input type="radio"/>                 |
|                                     | No <input checked="" type="radio"/>       |
| Collection date                     |   |
| Collection time                     |   |
| Collection date and time (derived)  |   |

US3602123

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

Form: Exposure

Data signed: (b) (4) 05 Apr 2021 21:30:03

Generated On: 10 Jun 2021 09:13:32

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 12 JAN 2021

What was the treatment time? (00:00-23:59) 16:25 (24 HR)

Treatment Date and Time (derived) 12 JAN 2021 16:25

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

US3602123

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 21:30:03

Generated On: 10 Jun 2021 09:13:32

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 JAN 2021

Collection time (00:00-23:59)

13:45 (24 HR)

Collection date and time (derived)

12 JAN 2021 13:45

US3602123

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Apr 2021 21:30:03

Generated On: 10 Jun 2021 09:13:32

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

|                               |             |
|-------------------------------|-------------|
| Collection date (dd MMM yyyy) | 12 JAN 2021 |
|-------------------------------|-------------|

|                                 |       |
|---------------------------------|-------|
| Collection time (00:00 - 23:59) | 13:50 |
|---------------------------------|-------|

|                                    |                   |
|------------------------------------|-------------------|
| Collection Date and Time (derived) | 12 JAN 2021 13:50 |
|------------------------------------|-------------------|



US3602123

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

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:30:03

Generated On: 10 Jun 2021 09:13:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602123

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:30:05

Generated On: 10 Jun 2021 09:13:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3602123

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:30:05

Generated On: 10 Jun 2021 09:13:32

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

US3602123

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 21:29:35

Generated On: 10 Jun 2021 09:13:32

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 9 FEB 2021                              |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | OLD29                                   |

US3602123

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Apr 2021 21:29:35

Generated On: 10 Jun 2021 09:13:32

|                                     |   |
|-------------------------------------|---|
| Timepoint                           | Pre-Dose <input checked="" type="radio"/> |
|                                     | Post-Dose <input type="radio"/>           |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>      |
|                                     | No <input type="radio"/>                  |
| Date of assessment (dd MMM yyyy)    | 9 FEB 2021                                |
| Time of assessment (00:00-23:59)    | 14:10 (24 HR)                             |
| Vital Signs Date and Time (derived) | 9 FEB 2021 14:10                          |
| Temperature (xxx.x)                 | 96.9 F                                    |
| Route of measurement                | Oral <input type="radio"/>                |
|                                     | Axillary <input type="radio"/>            |
|                                     | Other <input checked="" type="radio"/>    |
| If Other, specify                   | TEMPORAL/FOREHEAD<br>SCANNER WAS USED     |
| Pulse (xxx)                         | 76 beats/min                              |
| Pulse units                         | BPM                                       |
| Respiratory Rate (xxx)              | 16 breaths/min                            |
| Respiratory Rate units              | BREATHS/MIN                               |
| Systolic Blood Pressure (xxx)       | 136 mmHg                                  |
| Systolic Blood Pressure units       | MMHG                                      |
| Diastolic Blood Pressure (xxx)      | 76 mmHg                                   |
| Diastolic Blood Pressure units      | MMHG                                      |

US3602123

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 21:29:35

Generated On: 10 Jun 2021 09:13:32

|                                     |  |
|-------------------------------------|--|
| Timepoint                           | Pre-Dose <input type="radio"/>             |
|                                     | Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>       |
|                                     | No <input type="radio"/>                   |
| Date of assessment (dd MMM yyyy)    | 9 FEB 2021                                 |
| Time of assessment (00:00-23:59)    | 16:37 (24 HR)                              |
| Vital Signs Date and Time (derived) | 9 FEB 2021 16:37                           |
| Temperature (xxx.x)                 | 97.7 F                                     |
| Route of measurement                | Oral <input type="radio"/>                 |
|                                     | Axillary <input type="radio"/>             |
|                                     | Other <input checked="" type="radio"/>     |
| If Other, specify                   | TEMPORAL/FOREHEAD<br>SCANNER WAS USED      |
| Pulse (xxx)                         | 69 beats/min                               |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 18 breaths/min                             |
| Respiratory Rate units              | BREATHS/MIN                                |
| Systolic Blood Pressure (xxx)       | 120 mmHg                                   |
| Systolic Blood Pressure units       | MMHG                                       |
| Diastolic Blood Pressure (xxx)      | 85 mmHg                                    |
| Diastolic Blood Pressure units      | MMHG                                       |

US3602123

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 21:29:35

Generated On: 10 Jun 2021 09:13:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 FEB 2021

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

US3602123

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 05 Apr 2021 21:29:35

Generated On: 10 Jun 2021 09:13:32

|                                     |   |
|-------------------------------------|---|
| Was the pregnancy test performed?   | Yes <input checked="" type="radio"/>      |
|                                     | No <input type="radio"/>                  |
| Date of test ( <i>dd MMM yyyy</i> ) | 9 FEB 2021                                |
| Test performed                      | Urine <input checked="" type="radio"/>    |
|                                     | Serum <input type="radio"/>               |
| Result                              | Positive <input type="radio"/>            |
|                                     | Negative <input checked="" type="radio"/> |
| Was FSH sample collected?           | Yes <input type="radio"/>                 |
|                                     | No <input checked="" type="radio"/>       |
| Collection date                     |   |
| Collection time                     |   |
| Collection date and time (derived)  |   |



US3602123

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 05 Apr 2021 21:29:35

Generated On: 10 Jun 2021 09:13:32

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 9 FEB 2021

What was the treatment time? (00:00-23:59) 16:07 (24 HR)

Treatment Date and Time (derived) 9 FEB 2021 16:07

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

US3602123

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:29:35

Generated On: 10 Jun 2021 09:13:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3602123

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 21:30:05

Generated On: 10 Jun 2021 09:13:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 FEB 2021

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

*If Contact Not Made, please provide Comments*

ATTEMPTED TO REACH  
SUBJECT FOR DAY 36 OL PART  
B SAFETY CALL. CALLS MADE  
ON 2/16 AND 2/17. NO ANSWER.  
LEFT A MESSAGE TO CALL  
BACK STUDY TEAM

US3602123

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 21:30:05

Generated On: 10 Jun 2021 09:13:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3602123**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Data signed:** (b) (4) 05 Apr 2021 21:29:35

**Generated On: 10 Jun 2021 09:13:32**

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 10 MAR 2021                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | OLD57                                   |

US3602123

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 21:30:03

Generated On: 10 Jun 2021 09:13:32

|                                     |  |
|-------------------------------------|--|
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>   |
|                                     | No <input type="radio"/>               |
| Date of assessment (dd MMM yyyy)    | 10 MAR 2021                            |
| Time of assessment (00:00-23:59)    | 08:20 (24 HR)                          |
| Vital Signs Date and Time (derived) | 10 MAR 2021 08:20                      |
| Temperature (xxx.x)                 | 97.2 F                                 |
| Route of measurement                | Oral <input type="radio"/>             |
|                                     | Axillary <input type="radio"/>         |
|                                     | Other <input checked="" type="radio"/> |
| If Other, specify                   | TEMPORAL/FOREHEAD<br>SCANNER WAS USED  |
| Pulse (xxx)                         | 71 beats/min                           |
| Pulse units                         | BPM                                    |
| Respiratory Rate (xxx)              | 18 breaths/min                         |
| Respiratory Rate units              | BREATHS/MIN                            |
| Systolic Blood Pressure (xxx)       | 133 mmHg                               |
| Systolic Blood Pressure units       | MMHG                                   |
| Diastolic Blood Pressure (xxx)      | 74 mmHg                                |
| Diastolic Blood Pressure units      | MMHG                                   |
| Height (derived)                    |  |
| Weight (derived)                    |  |

US3602123

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 21:29:35

Generated On: 10 Jun 2021 09:13:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 MAR 2021

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

US3602123

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 21:29:35

Generated On: 10 Jun 2021 09:13:32

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

|                               |             |
|-------------------------------|-------------|
| Collection date (dd MMM yyyy) | 10 MAR 2021 |
|-------------------------------|-------------|

|                               |               |
|-------------------------------|---------------|
| Collection time (00:00-23:59) | 08:40 (24 HR) |
|-------------------------------|---------------|

|                                    |                   |
|------------------------------------|-------------------|
| Collection date and time (derived) | 10 MAR 2021 08:40 |
|------------------------------------|-------------------|



US3602123

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 17:45:26

Generated On: 10 Jun 2021 09:13:32

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3602123

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 05 Apr 2021 21:29:34

Generated On: 10 Jun 2021 09:13:32

AEID

Adverse event

SHOULDER PAIN \_ L SIDED

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

9 OCT 2020

Start time (00:00-23:59)

07:00 (24 HR)

AE start date and time (derived)

9 OCT 2020 07:00

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

19 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

377 of 2529

EAB) (1725)

US3602123

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 05 Apr 2021 21:29:34

Generated On: 10 Jun 2021 09:13:32

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

US3602123

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 05 Apr 2021 21:29:34

Generated On: 10 Jun 2021 09:13:32

|  |  |
|--|--|
| AEID   | USA-US079-2021-MRNA-1273-P30<br>1000002  |
| Adverse event  | WORSENING OF IMMUNE<br>THROMBOCYTOPENIA  |
| 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)                                       | 12 FEB 2021  |
| 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)                         | 15 FEB 2021  |
| End time (00:00-23:59)   |  |
| AE End Date and Time (derived)                                 |  |
| Severity   | Grade 1/Mild <input type="radio"/><br>Grade 2/Moderate <input type="radio"/><br>Grade 3/Severe <input checked="" 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 | False  |
| Hospital Admission Date (dd MMM yyyy)                          |  |
| Hospital Discharge Date (dd MMM yyyy)                          |  |
| Admitted to ICU?   | Yes <input type="radio"/><br>No <input type="radio"/><br>Unknown <input type="radio"/>   |
| PRODUCTION RELEASE (v12.003<br>EAB) (1725)                     | 379 of 2529  |

US3602123

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 05 Apr 2021 21:29:34

Generated On: 10 Jun 2021 09:13:32

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

US3602123

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 05 Apr 2021 21:29:34

Generated On: 10 Jun 2021 09:13:32

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PT WITH KNOWN ITP HISTORY  
FOR YEARS AND WENT FOR  
ROUTINE HEMATOLOGY VISIT  
ON FEB 9TH AND WAS NOTED  
TO HAVE SLIGHTLY LOWER  
PLATELET COUNT AND ALSO  
SHINGLES IN THE BUTTOCK  
AND WAS PRESCRIBED  
VALTREX . SHE THEN  
RECEIVED A SECOND DOSE OF  
THE MRNA 1273 AT 2PM ON 2/9/  
20 AND ON REPEAT TESTS ON  
2/12 SHE HAD A VERY  
SIGNIFICANT DROP IN THE  
PLATELETS TO 28K AND THIS  
WAS REPEAT AGAIN TODAY (   
2/15 ) AND WITH SOME  
IMPROVEMENT TO 68 K . SHE  
WILL BE AGAIN SEEN BY THE  
HEMATOLOGIST NEXT WEEK  
FOR THE SAME .

NO MEDS GIVEN FOR THE ITP  
ACUTE ATTACK  
I DISCUSSED WITH THE  
HEMATOLOGIST WHO FEELS  
THAT IT IS UNKNOWN IF THIS  
IS IMMUNE MEDIATED POST  
VACCINE VERSUS RELATED TO  
THE SHINGLES OUTBREAK  
THAT OCCURRED THE SAME  
TIME TEMPORALLY. SUBJECT  
PLATELETS WERE BACK UP TO  
92K ON 2/15/21

---

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

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Folder: Adverse Events

Form: Adverse Events (6)

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AEID

Adverse event

PRESUMPTIVE SHINGLES

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

10 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

11 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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|   |   |
|---|---|
| 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 <input type="radio"/><br>Withdrawn <input type="radio"/><br>Not Applicable <input type="radio"/>   |
| Other action taken (check all that apply)   |   |
| None  | False   |
| Concomitant Medication  | True  |
| Concomitant Procedure   | False   |
| Outcome   | Fatal <input type="radio"/><br>Not Recovered/Not Resolved <input type="radio"/><br>Recovered/Resolved <input checked="" type="radio"/><br>Recovered/Resolved with Sequelae <input type="radio"/><br>Recovering/Resolving <input type="radio"/><br>Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:<br>_____ |   |
| Narrative<br>_____  |   |
| Serious Adverse Event Derived (CSA Programming Field Only)                            | 0   |
| Medically Attended AE Derived (CSA Programming Field Only)                            | 1   |
| Admitted to ICU Derived (CSA Programming Field Only)                                  | _____   |



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|  |  |
|--|--|
| AEID   | USA-US079-2021-MRNA-1273-P30<br>1000002  |
| Adverse event  | SIGNIFICANT DROP OF THE<br>PLATELET COUNT  |
| 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)                                       | 12 FEB 2021  |
| 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)                         | 15 FEB 2021  |
| End time (00:00-23:59)   |  |
| AE End Date and Time (derived)                                 |  |
| Severity   | Grade 1/Mild <input type="radio"/><br>Grade 2/Moderate <input type="radio"/><br>Grade 3/Severe <input checked="" 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 | False  |
| Hospital Admission Date (dd MMM yyyy)                          |  |
| Hospital Discharge Date (dd MMM yyyy)                          |  |
| Admitted to ICU?   | Yes <input type="radio"/><br>No <input type="radio"/><br>Unknown <input type="radio"/>   |
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|  |   |
|--|---|
| Number of Days in ICU  |   |
| Persistent or significant disability or incapacity                           | False   |
| Congenital anomaly or birth defect   | False   |
| Other medically important event  | True  |
| Relationship to investigational product                                      | Not Related <input checked="" type="radio"/><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 type="radio"/><br>Dose Delayed <input type="radio"/><br>Investigational Product Withdrawn <input type="radio"/><br>Not Applicable <input checked="" type="radio"/>  |
| Other action taken (check all that apply)                                    |   |
| None   | True  |
| Concomitant Medication   | False   |
| Concomitant Procedure  | False   |
| Outcome  | Fatal <input type="radio"/><br>Not Recovered/Not Resolved <input type="radio"/><br>Recovered/Resolved <input checked="" type="radio"/><br>Recovered/Resolved with Sequelae <input type="radio"/><br>Recovering/Resolving <input type="radio"/><br>Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: |   |
| Narrative  |   |

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Folder: Adverse Events

Form: Adverse Events (7)

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PT WITH KNOWN ITP HISTORY  
FOR YEARS AND WENT FOR  
ROUTINE HEMATOLOGY VISIT  
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NO MEDS GIVEN FOR THE ITP  
ACUTE ATTACK  
I DISCUSSED WITH THE  
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PLATELETS WERE BACK UP TO  
92K ON 2/15/21

---

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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Name of Medication MINASTRIM 28 DAY CYCLE

Prophylaxis Yes ☐  
No ☒

Indication FOR CONTRACEPTION

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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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)                           | UN UNK 2017              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   | 1                        |                                  |
| Interval Dosage Unit Number (derived)              | 1                        |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

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Name of Medication AMLODIPINE

Prophylaxis Yes ☐  
No ☒

Indication FOR HTN

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)

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



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

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Name of Medication PHENTERMINE

Prophylaxis Yes ☒  
No ☐

Indication DIETARY SUPPLEMENT TO  
PREVENT WEIGHT GAIN

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 (3)

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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) _____                     |                          |                                     |
| Start date completely unknown                      |                          | True                                |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 28 SEP 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 (4)

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Name of Medication ZYRTEC

Prophylaxis Yes ☐  
No ☒

Indication FOR SEASONAL ALLERGIES

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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|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intramuscular            | <input type="checkbox"/>         |
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | UN UNK 2018              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   | 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 (5)

Data signed: (b) (4) 02 May 2021 01:32:34

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Name of Medication VITAMIN C

Prophylaxis Yes ☒  
No ☐

Indication FOR SUPPLEMENT

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 ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

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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)                           | UN UNK 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 (6)

Data signed: (b) (4) 02 May 2021 01:32:34

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Name of Medication MAGNESIUM

Prophylaxis Yes ☒  
No ☐

Indication FOR SUPPLEMENT

Dose per administration 450

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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Form: Prior/Concomitant Medication and Vaccination (6)

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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)                           | UN UNK 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 (7)

Data signed: (b) (4) 02 May 2021 01:32:34

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Name of Medication POTASSIUM

Prophylaxis Yes ☒  
No ☐

Indication FOR SUPPLEMENT

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 02 May 2021 01:32:34

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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)                           | UN UNK 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 (8)

Data signed: (b) (4) 02 May 2021 01:32:34

Generated On: 10 Jun 2021 09:13:32

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE DURING DAY 5  
REPORTED ON SAFETY CALL  
DAY 8 - A.E

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 (8)

Data signed: (b) (4) 02 May 2021 01:32:34

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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)                       | 5 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)         | 6 OCT 2020               |                                     |
| Was this medication taken for solicited event? | Yes                      | <input checked="" type="checkbox"/> |
|  | No                       | <input 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 (9)

Data signed: (b) (4) 02 May 2021 01:32:34

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Name of Medication TUMS

Prophylaxis Yes ☐  
No ☒

Indication A.E: QUEASY STOMACH -  
REPORTED IN SAFETY DAY #8

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 02 May 2021 01:32:34

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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)                           |                          | 7 OCT 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)                   |                          | 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 (10)

Data signed: (b) (4) 02 May 2021 01:32:34

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Name of Medication TUMS

Prophylaxis Yes ☐  
No ☒

Indication A.E: HEART BURN - REPORTED  
IN SAFETY DAY #8

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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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)                           |                          | 7 OCT 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)                   |                          | 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 (11)

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Name of Medication TYLENOL EXTRA STRENGTH

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE - REPORTED FOR  
DIARY DOSE 1 ON DAY 5 ON  
10/6 VIA E-DIARY

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 (11)

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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)                       | 6 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)         |                          | 6 OCT 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 (12)

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Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication FEVER 100.7, HEADACHE,  
REDNESS TO LEFT ARM -  
INJECTION SITE, SWELLING TO  
LEFT ARM - INJECTION SITE,  
PAIN TO LEFT ARM -  
INJECTION SITE, TENDERNESS  
TO LEFT ARM - INJECTION SITE,  
BRUISE TO LEFT ARM

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

X Q12 X 5 DOSES

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Form: Prior/Concomitant Medication and Vaccination (12)

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|  |                           |                                     |
|--|---------------------------|-------------------------------------|
| Route of administration                            | Oral                      | <input checked="" type="radio"/>    |
|  | Topical                   | <input type="radio"/>               |
|  | Subcutaneous              | <input type="radio"/>               |
|  | Transdermal               | <input type="radio"/>               |
|  | 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 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)                           | 10 FEB 2021               |                                     |
| Start date completely unknown                      | False                     |                                     |
| Ongoing?   | Yes <input type="radio"/> | No <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) 12 FEB 2021 |                           |                                     |
| 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 (13)

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Name of Medication NYQUIL (UNKNOWN)

Prophylaxis Yes ☐  
No ☒

Indication FEVER 100.7

Dose per administration 2

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

If dose unit is Other, specify TABLESPOON

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 X Q12 X 3 DOSES

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

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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)                           |                          | 10 FEB 2021                         |
| Start date completely unknown                      |                          | False                               |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) 12 FEB 2021 |                          |                                     |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____             |                          |                                     |
| Interval Dosage Unit Number (derived) _____        |                          |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input type="checkbox"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 02 May 2021 01:32:34

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Name of Medication VALTREX (VALACYCLOVIR  
HYDROCHLORIDE)

Prophylaxis Yes ☐  
No ☒

Indication PRESUMPTIVE SHINGLES

Dose per administration 1

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

If dose unit is Other, specify GM

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)                       | 9 FEB 2021               |                                     |
| Start date completely unknown                  | False                    |                                     |
| Ongoing?                                       | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)         | 16 FEB 2021              |                                     |
| Was this medication taken for solicited event? | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)               | 3                        |                                     |
| Interval Dosage Unit Number (derived)          | 1                        |                                     |
| Interval Dosage Definition (derived)           | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input checked="" type="checkbox"/> |



US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 02 May 2021 01:32:34

Generated On: 10 Jun 2021 09:13:32

Name of Medication VITAMIN D

Prophylaxis Yes ☒  
No ☐

Indication BORDERLINE LOW VITAMIN D  
DEFICIENCY

Dose per administration 2000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

416 of 2529

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 02 May 2021 01:32:34

Generated On: 10 Jun 2021 09:13:32

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | 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)                           |                          | 25 APR 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)                   |                          | 1                                |
| Interval Dosage Unit Number (derived)              |                          | 1                                |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input checked="" type="radio"/> |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 02 May 2021 01:32:34

Generated On: 10 Jun 2021 09:13:32

Name of Medication ROSUVASTATIN

Prophylaxis Yes ☒  
No ☐

Indication BORDERLINE HIGH  
CHOLESTEROL

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

418 of 2529

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 02 May 2021 01:32:34

Generated On: 10 Jun 2021 09:13:32

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | 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)                           |                          | 25 APR 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)                   |                          | 1                                |
| Interval Dosage Unit Number (derived)              |                          | 1                                |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input checked="" type="radio"/> |

US3602123

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Apr 2021 21:29:35

Generated On: 10 Jun 2021 09:13:32

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3602123

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 05 Apr 2021 21:29:35

Generated On: 10 Jun 2021 09:13:32

| Procedure/Surgery date (dd MMM<br>yyyy) | Procedure/Surgery | Indication    | If indication is Other, specify |
|---|-------------------|---------------|---------------------------------|
| 9 FEB 2021                              | BLOOD WORK        | Adverse Event |                                 |
| 12 FEB 2021                             | BLOOD WORK        | Adverse Event |                                 |
| 15 FEB 2021                             | BLOOD WORK-UP     | Adverse Event |                                 |

US3602123

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:13:32

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify

US3602123

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:13:32

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 ☐



US3602123

Folder: SAE USA-US079-2021-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 05 Apr 2021 21:30:04

Generated On: 10 Jun 2021 09:13:32

|  |  |
|--|--|
| SAEID  | USA-US079-2021-MRNA-1273-P301000002                              |
| 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 type="radio"/><br>No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity             | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                             | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event                                | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Investigator's First Name                                      | BINDU  |
| Investigator's Last Name                                       | BALANI   |
| Site Address: Street   |  |
| Site Address: City   |  |
| Site Address: State  | NJ   |
| Site Address: Postal Code                                      |  |
| Investigator Country   | US   |
| E2B Transmit Flag (Derived/Hidden)                             | 8  |

US3602123

Folder: SAE USA-US079-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 05 Apr 2021 21:30:04

Generated On: 10 Jun 2021 09:13:32

|   |  |
|---|--|
| SAEID   | USA-US079-2021-MRNA-1273-P301000002                              |
| 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 type="radio"/><br>No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event   | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Investigator's First Name   | BINDU  |
| Investigator's Last Name  | BALANI   |
| Site Address: Street  |  |
| Site Address: City  |  |
| Site Address: State   | NJ   |
| Site Address: Postal Code   |  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 8  |
| Date of submission (Pre-filled from custom function)  | 17/FEB/2021 09:55  |
| 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   |

US3602123

Folder: SAE USA-US079-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 05 Apr 2021 21:30:04

Generated On: 10 Jun 2021 09:13:32

|   |  |
|---|--|
| SAEID   | USA-US079-2021-MRNA-1273-P301000002                              |
| 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 type="radio"/><br>No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event   | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Investigator's First Name   | BINDU  |
| Investigator's Last Name  | BALANI   |
| Site Address: Street  |  |
| Site Address: City  |  |
| Site Address: State   | NJ   |
| Site Address: Postal Code   |  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 8  |
| Date of submission (Pre-filled from custom function)  | 23/FEB/2021 10:17  |
| 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   |

US3602123

Folder: SAE USA-US079-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 05 Apr 2021 21:30:04

Generated On: 10 Jun 2021 09:13:32

|   |  |
|---|--|
| SAEID   | USA-US079-2021-MRNA-1273-P301000002                              |
| 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 type="radio"/><br>No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event   | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Investigator's First Name   | BINDU  |
| Investigator's Last Name  | BALANI   |
| Site Address: Street  |  |
| Site Address: City  |  |
| Site Address: State   | NJ   |
| Site Address: Postal Code   |  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 8  |
| Date of submission (Pre-filled from custom function)  | 26/FEB/2021 10:54  |
| 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   |

US3602123

Folder: SAE USA-US079-2021-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) 05 Apr 2021 21:30:04

Generated On: 10 Jun 2021 09:13:32

|   |  |
|---|--|
| SAEID   | USA-US079-2021-MRNA-1273-P301000002                              |
| 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 type="radio"/><br>No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event   | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Investigator's First Name   | BINDU  |
| Investigator's Last Name  | BALANI   |
| Site Address: Street  |  |
| Site Address: City  |  |
| Site Address: State   | NJ   |
| Site Address: Postal Code   |  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 8  |
| Date of submission (Pre-filled from custom function)  | 01/MAR/2021 09:38  |
| 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   |

US3602123

Folder: SAE USA-US079-2021-MRNA-1273-P301000002

Form: Safety Report Form (5)

Data signed: (b) (4) 05 Apr 2021 21:30:04

Generated On: 10 Jun 2021 09:13:32

|   |  |
|---|--|
| SAEID   | USA-US079-2021-MRNA-1273-P301000002                              |
| 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 type="radio"/><br>No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event   | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Investigator's First Name   | BINDU  |
| Investigator's Last Name  | BALANI   |
| Site Address: Street  |  |
| Site Address: City  |  |
| Site Address: State   | NJ   |
| Site Address: Postal Code   |  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 8  |
| Date of submission (Pre-filled from custom function)  | 09/MAR/2021 06:24  |
| 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   |

US3602123

Folder: SAE USA-US079-2021-MRNA-1273-P301000002

Form: Safety Report Form (6)

Data signed: (b) (4) 05 Apr 2021 21:30:04

Generated On: 10 Jun 2021 09:13:32

|   |  |
|---|--|
| SAEID   | USA-US079-2021-MRNA-1273-P301000002                              |
| 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 type="radio"/><br>No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event   | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Investigator's First Name   | BINDU  |
| Investigator's Last Name  | BALANI   |
| Site Address: Street  |  |
| Site Address: City  |  |
| Site Address: State   | NJ   |
| Site Address: Postal Code   |  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 8  |
| Date of submission (Pre-filled from custom function)  | 10/MAR/2021 10:41  |
| 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   |

US3602123

Folder: SAE USA-US079-2021-MRNA-1273-P301000002

Form: Safety Report Form (7)

Data signed: (b) (4) 05 Apr 2021 21:30:04

Generated On: 10 Jun 2021 09:13:32

|   |  |
|---|--|
| SAEID   | USA-US079-2021-MRNA-1273-P301000002                              |
| 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 type="radio"/><br>No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event   | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Investigator's First Name   | BINDU  |
| Investigator's Last Name  | BALANI   |
| Site Address: Street  |  |
| Site Address: City  |  |
| Site Address: State   | NJ   |
| Site Address: Postal Code   |  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 8  |
| Date of submission (Pre-filled from custom function)  | 17/MAR/2021 15:52  |
| 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   |



US3602123

Folder: SAE USA-US079-2021-MRNA-1273-P301000002

Form: Safety Report Form (8)

Data signed: (b) (4) 05 Apr 2021 21:30:04

Generated On: 10 Jun 2021 09:13:32

|   |  |
|---|--|
| SAEID   | USA-US079-2021-MRNA-1273-P301000002                              |
| 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 type="radio"/><br>No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event   | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Investigator's First Name   | BINDU  |
| Investigator's Last Name  | BALANI   |
| Site Address: Street  |  |
| Site Address: City  |  |
| Site Address: State   | NJ   |
| Site Address: Postal Code   |  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 8  |
| Date of submission (Pre-filled from custom function)  | 22/MAR/2021 14:46  |
| 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

US3602123 (Prod: Hackensack University Medical Center)

**US3602123**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 09:13:32**

[Participant ID](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)                        | 05 Apr 2021 21:29:37 |
| User entered 'US3602123'  | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 02 Oct 2020 17:17:43 |

**US3602123**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:32**

[Was this visit performed?](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:15 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)     | 02 Oct 2020 19:43:49 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:13:32

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

| Audit                      | User                 | Time (GMT)           |
|----------------------------|----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                            |                      |                      |
| Data hard unlocked.        | (b) (4), (b) (6)     | 02 May 2021 07:01:15 |
|                            |                      |                      |
| Data hard locked.          | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                            |                      |                      |
| User signature succeeded.  | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                            | (b) (4)              |                      |
| User entered '02 OCT 2020' | RWS_ENDPOINT         | 02 Oct 2020 17:17:44 |
|                            | ENDPOINT (b) (4)     |                      |
|                            |                      |                      |

US3602123

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:13:32

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

| Audit                          | User                 | Time (GMT)           |
|--------------------------------|----------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                                |                      |                      |
| Data hard unlocked.            | (b) (4), (b) (6)     | 02 May 2021 07:01:15 |
|                                |                      |                      |
| Data hard locked.              | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                                |                      |                      |
| User signature succeeded.      | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                                | (b) (4)              |                      |
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6)     | 02 Oct 2020 19:43:49 |
|                                |                      |                      |

**US3602123**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:32**

[Folder OID](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 02 May 2021 07:01:15 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                     |                  |                      |
| User entered 'SCRN' | System           | 02 Oct 2020 19:43:49 |

US3602123

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:13:32

Date of Birth (MMM yyyy)

| Audit                      | User                 | Time (GMT)           |
|----------------------------|----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                            |                      |                      |
| Data hard unlocked.        | (b) (4), (b) (6)     | 02 May 2021 07:01:19 |
|                            |                      |                      |
| Data hard locked.          | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                            |                      |                      |
| User signature succeeded.  | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                            | (b) (4)              |                      |
| User entered (b) (6) 1973' | RWS_ENDPOINT         | 02 Oct 2020 17:17:46 |
|                            | ENDPOINT (b) (4)     |                      |
|                            |                      |                      |



US3602123

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:13:32

[Age](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:19 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered '46'         | (b) (4), (b) (6)     | 02 Oct 2020 19:45:05 |
|                           |                      |                      |

**US3602123**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:32**

[Age Units](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                      |                  |                      |
| Data hard unlocked.  | (b) (4), (b) (6) | 02 May 2021 07:01:19 |
|                      |                  |                      |
| Data hard locked.    | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                      |                  |                      |
| User entered 'YEARS' | System           | 02 Oct 2020 19:45:05 |

**US3602123**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:32**

[Age \(Derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 02 May 2021 07:01:19 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                     |                  |                      |
| User entered '46'   | System           | 02 Oct 2020 19:45:43 |

**US3602123**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:32**

[Sex](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:19 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered 'Female (F)' | (b) (4), (b) (6)     | 02 Oct 2020 19:45:05 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:13:32

[Ethnicity](#)

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|  |                      |                      |
| Data hard unlocked.                                    | (b) (4), (b) (6)     | 02 May 2021 07:01:19 |
|  |                      |                      |
| Data hard locked.                                      | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|  |                      |                      |
| User signature succeeded.                              | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|  | (b) (4)              |                      |
| User entered 'Hispanic or Latino (HISPANIC OR LATINO)' | (b) (4), (b) (6)     | 02 Oct 2020 19:45:05 |
|  |                      |                      |

**US3602123**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:32**

[White](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:19 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered 'I'          | (b) (4), (b) (6)     | 02 Oct 2020 19:45:05 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:13:32

[Black](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:19 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered '0'          | (b) (4), (b) (6)     | 02 Oct 2020 19:45:05 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:13:32

[Asian](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:19 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered '0'          | (b) (4), (b) (6)     | 02 Oct 2020 19:45:05 |
|                           |                      |                      |



US3602123

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:13:32

[American Indian or Alaska Native](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:19 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered '0'          | (b) (4), (b) (6)     | 02 Oct 2020 19:45:05 |
|                           |                      |                      |

**US3602123**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:32**

[Native Hawaiian or other Pacific Islander](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:19 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered '0'          | (b) (4), (b) (6)     | 02 Oct 2020 19:45:05 |
|                           |                      |                      |

**US3602123**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:32**

[Other](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:19 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered '0'          | (b) (4), (b) (6)     | 02 Oct 2020 19:45:05 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:13:32

If race is Other, specify

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:19 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered empty.       | (b) (4), (b) (6)     | 02 Oct 2020 19:45:05 |
|                           |                      |                      |

**US3602123**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:13:32**

[Unknown](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:19 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered '0'          | (b) (4), (b) (6)     | 02 Oct 2020 19:45:05 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:13:32

Not reported

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:19 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered '0'          | (b) (4), (b) (6)     | 02 Oct 2020 19:45:05 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:13:32

Date of Informed Consent (*dd MMM yyyy*)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:24 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered '2 Oct 2020' | (b) (4), (b) (6)     | 02 Oct 2020 19:45:43 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:13:32

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                         |                  |                      |
| Data hard unlocked.     | (b) (4), (b) (6) | 02 May 2021 07:01:24 |
|                         |                  |                      |
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                         |                  |                      |
| User entered 'Oct 2020' | System           | 02 Oct 2020 19:45:43 |



US3602123

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:13:32

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 02 May 2021 07:01:24 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                     |                  |                      |
| User entered '2020' | System           | 02 Oct 2020 19:45:43 |

**US3602123**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:13:32**

[Protocol Version](#)

| Audit                          | User                 | Time (GMT)           |
|--------------------------------|----------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                                |                      |                      |
| Data hard unlocked.            | (b) (4), (b) (6)     | 02 May 2021 07:01:24 |
|                                |                      |                      |
| Data hard locked.              | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                                |                      |                      |
| User signature succeeded.      | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                                | (b) (4)              |                      |
| User entered 'Amendment 3 (3)' | (b) (4), (b) (6)     | 02 Oct 2020 19:45:43 |
|                                |                      |                      |

US3602123

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:13:32

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

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:24 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)     | 02 Oct 2020 19:45:43 |
|                           |                      |                      |

**US3602123**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:13:32**

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

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:24 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered empty.       | (b) (4), (b) (6)     | 02 Oct 2020 19:45:43 |
|                           |                      |                      |

**US3602123**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:13:32**

If reason for screen fail is Other, specify

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:24 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered empty.       | (b) (4), (b) (6)     | 02 Oct 2020 19:45:43 |
|                           |                      |                      |

**US3602123**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:13:32**

[Was this participant screened previously?](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:24 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)     | 02 Oct 2020 19:45:43 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:13:32

[If Yes, previous participant number](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:24 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered empty.       | RWS_ENDPOINT         | 02 Oct 2020 17:17:44 |
|                           | ENDPOINT (b) (4)     |                      |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:13:32

[Enrollment Trigger](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 02 May 2021 07:01:24 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                     |                  |                      |
| User entered 'I'    | System           | 02 Oct 2020 19:46:12 |



**US3602123**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 10 Jun 2021 09:13:32**

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

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:28 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)     | 02 Oct 2020 19:46:12 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:13:32

[Were any significant conditions reported?](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:33 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)     | 02 Oct 2020 20:51:46 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:13:32

Condition

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
| Data hard unlocked.  | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
| Data hard locked.  | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
| Data hard unlocked.  | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
| Data hard locked.  | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
| User signature succeeded.  | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
| DataPoint Verified.  | (b) (4), (b) (6)     | 11 Mar 2021 15:33:07 |
| User closed query 'Per progress note from SAE, it appears she subject had shingles on the buttocks. Verify if Shingles should be added to Medical Hx and update data accordingly.' (Site from CRA). Query 'Per progress note from SAE, it appears she subject had shingles on the buttocks. Verify if Shingles should be added to Medical Hx and update data accordingly.' answered with 'Per source it was 'PRESUMPTIVE SHINGLES'. Added as an A.E.' (Site from CRA). | (b) (4), (b) (6)     | 11 Mar 2021 15:33:03 |
| User opened query 'Per progress note from SAE, it appears she subject had shingles on the buttocks. Verify if Shingles should be added to Medical Hx and update data accordingly.' (Site from CRA).  | (b) (4), (b) (6)     | 22 Feb 2021 20:58:50 |
| User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.  | Coder Import (b) (4) | 03 Oct 2020 07:05:45 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.   | (b) (4)              | 03 Oct 2020 07:05:45 |
| Data point term sent to Coder  | System               | 02 Oct 2020 20:53:11 |
| User entered 'Hypertension controlled with oral medication'  | (b) (4), (b) (6)     | 02 Oct 2020 20:52:28 |

US3602123

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:13:32

Start date (dd MMM yyyy)

| Audit                      | User                 | Time (GMT)           |
|----------------------------|----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                            |                      |                      |
| Data hard unlocked.        | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|                            |                      |                      |
| Data hard locked.          | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|                            |                      |                      |
| Data hard unlocked.        | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|                            |                      |                      |
| Data hard locked.          | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                            |                      |                      |
| User signature succeeded.  | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                            | (b) (4)              |                      |
| DataPoint Verified.        | (b) (4), (b) (6)     | 11 Mar 2021 15:33:07 |
|                            |                      |                      |
| User entered 'un UNK 2018' | (b) (4), (b) (6)     | 02 Oct 2020 20:52:28 |
|                            |                      |                      |

US3602123

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:13:32

Start date completely unknown

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| DataPoint Verified.       | (b) (4), (b) (6)     | 11 Mar 2021 15:33:07 |
|                           |                      |                      |
| User entered '0'          | (b) (4), (b) (6)     | 02 Oct 2020 20:52:28 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:13:32

[Condition ongoing at study entry](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| DataPoint Verified.       | (b) (4), (b) (6)     | 11 Mar 2021 15:33:07 |
|                           |                      |                      |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)     | 02 Oct 2020 20:52:28 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:13:32

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

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| DataPoint Verified.       | (b) (4), (b) (6)     | 11 Mar 2021 15:33:07 |
|                           |                      |                      |
| User entered empty.       | (b) (4), (b) (6)     | 02 Oct 2020 20:52:28 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:13:32

[Stop date completely unknown](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| DataPoint Verified.       | (b) (4), (b) (6)     | 11 Mar 2021 15:33:07 |
|                           |                      |                      |
| User entered '0'          | (b) (4), (b) (6)     | 02 Oct 2020 20:52:28 |
|                           |                      |                      |



US3602123

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:13:32

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                         |                  |                      |
| Data hard unlocked.     | (b) (4), (b) (6) | 02 May 2021 07:01:38 |
|                         |                  |                      |
| Data hard locked.       | (b) (4), (b) (6) | 01 May 2021 20:11:02 |
|                         |                  |                      |
| Data hard unlocked.     | (b) (4), (b) (6) | 30 Apr 2021 11:44:18 |
|                         |                  |                      |
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                         |                  |                      |
| User entered 'Jan 2018' | System           | 02 Oct 2020 20:52:28 |

**US3602123**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:13:32**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 02 May 2021 07:01:38 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 20:11:02 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 30 Apr 2021 11:44:18 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                     |                  |                      |
| User entered '2018' | System           | 02 Oct 2020 20:52:28 |

US3602123

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:13:32

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 02 May 2021 07:01:38 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 20:11:02 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 30 Apr 2021 11:44:18 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                     |                  |                      |
| User entered empty. | System           | 02 Oct 2020 20:52:28 |

US3602123

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:13:32

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 02 May 2021 07:01:38 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 20:11:02 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 30 Apr 2021 11:44:18 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                     |                  |                      |
| User entered empty. | System           | 02 Oct 2020 20:52:28 |

US3602123

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:13:32

Condition

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|  | (b) (4), (b) (6)     |                      |
| Data hard unlocked.  | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|  | (b) (4), (b) (6)     |                      |
| Data hard locked.  | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|  | (b) (4), (b) (6)     |                      |
| Data hard unlocked.  | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|  | (b) (4), (b) (6)     |                      |
| Data hard locked.  | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|  | (b) (4), (b) (6)     |                      |
| User signature succeeded.  | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|  | (b) (4)              |                      |
| DataPoint Verified.  | (b) (4), (b) (6)     | 18 Feb 2021 18:32:32 |
|  | (b) (4), (b) (6)     |                      |
| User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Platelet disorders, HLT: Thrombocytopenias, PT: Immune thrombocytopenia, LLT: Immune thrombocytopenia - version MedDRA\23.0. | Coder Import (b) (4) | 23 Nov 2020 12:16:56 |
|  | (b) (4)              |                      |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.   | Coder Import (b) (4) | 23 Nov 2020 12:16:56 |
|  | (b) (4)              |                      |
| Data point term sent to Coder  | System               | 05 Nov 2020 18:04:36 |
| User closed query 'For coding purposes, please clarify the abbreviation ITP.' (Site from System).  | System               | 05 Nov 2020 18:03:40 |
| Query 'For coding purposes, please clarify the abbreviation ITP.' answered with 'Updated' (Site from System).  | (b) (4), (b) (6)     | 05 Nov 2020 18:03:40 |
|  | (b) (4), (b) (6)     |                      |
| Data point term sent to Coder  | System               | 05 Nov 2020 18:03:35 |
| Coding entries removed.  | (b) (4), (b) (6)     | 05 Nov 2020 18:03:33 |
|  | (b) (4), (b) (6)     |                      |
| User entered 'Immune thromobcytopenia' reason for change: Per Query Resolution   | (b) (4), (b) (6)     | 05 Nov 2020 18:03:33 |
|  | (b) (4), (b) (6)     |                      |
| User closed query 'Per MM, please expand the abbreviation' (Site from DM).   | (b) (4), (b) (6)     | 28 Oct 2020 21:52:58 |
|  | (b) (4), (b) (6)     |                      |
| User opened query 'For coding purposes, please clarify the abbreviation ITP.' (Site from System).  | Coder Import (b) (4) | 27 Oct 2020 18:08:23 |
|  | (b) (4)              |                      |
| Query 'Per MM, please expand the abbreviation' answered with 'Info acquired from EMR, inserted as such' (Site from DM).  | (b) (4), (b) (6)     | 27 Oct 2020 16:07:14 |
|  | (b) (4), (b) (6)     |                      |
| User opened query 'Per MM, please expand the abbreviation' (Site from DM).   | (b) (4), (b) (6)     | 19 Oct 2020 13:51:14 |
|  | (b) (4), (b) (6)     |                      |

US3602123

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:13:32

Condition

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Platelet disorders, HLT: Thrombocytopenias, PT: Immune thrombocytopenia, LLT: Idiopathic thrombocytopenic purpura - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4) | 03 Oct 2020 07:02:44 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.   | Coder Import (b) (4)<br>(b) (4) | 03 Oct 2020 07:02:44 |
| Data point term sent to Coder   | System                          | 02 Oct 2020 20:53:12 |
| User entered 'TTP'  | (b) (4), (b) (6)                | 02 Oct 2020 20:52:42 |

**US3602123**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:13:32**

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

| Audit                      | User                 | Time (GMT)           |
|----------------------------|----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                            |                      |                      |
| Data hard unlocked.        | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|                            |                      |                      |
| Data hard locked.          | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|                            |                      |                      |
| Data hard unlocked.        | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|                            |                      |                      |
| Data hard locked.          | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                            |                      |                      |
| User signature succeeded.  | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                            | (b) (4)              |                      |
| DataPoint Verified.        | (b) (4), (b) (6)     | 18 Feb 2021 18:32:32 |
|                            |                      |                      |
| User entered 'un UNK 1999' | (b) (4), (b) (6)     | 02 Oct 2020 20:52:42 |
|                            |                      |                      |

**US3602123**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Start date completely unknown](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| DataPoint Verified.       | (b) (4), (b) (6)     | 18 Feb 2021 18:32:32 |
|                           |                      |                      |
| User entered '0'          | (b) (4), (b) (6)     | 02 Oct 2020 20:52:42 |
|                           |                      |                      |



US3602123

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:13:32

[Condition ongoing at study entry](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| DataPoint Verified.       | (b) (4), (b) (6)     | 18 Feb 2021 18:32:32 |
|                           |                      |                      |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)     | 02 Oct 2020 20:52:42 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:13:32

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

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| DataPoint Verified.       | (b) (4), (b) (6)     | 18 Feb 2021 18:32:32 |
|                           |                      |                      |
| User entered empty.       | (b) (4), (b) (6)     | 02 Oct 2020 20:52:42 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:13:32

[Stop date completely unknown](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| DataPoint Verified.       | (b) (4), (b) (6)     | 18 Feb 2021 18:32:32 |
|                           |                      |                      |
| User entered '0'          | (b) (4), (b) (6)     | 02 Oct 2020 20:52:42 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:13:32

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                         |                  |                      |
| Data hard unlocked.     | (b) (4), (b) (6) | 02 May 2021 07:01:38 |
|                         |                  |                      |
| Data hard locked.       | (b) (4), (b) (6) | 01 May 2021 20:11:02 |
|                         |                  |                      |
| Data hard unlocked.     | (b) (4), (b) (6) | 30 Apr 2021 11:44:18 |
|                         |                  |                      |
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                         |                  |                      |
| User entered 'Jan 1999' | System           | 02 Oct 2020 20:52:42 |

US3602123

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:13:32

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 02 May 2021 07:01:38 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 20:11:02 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 30 Apr 2021 11:44:18 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                     |                  |                      |
| User entered '1999' | System           | 02 Oct 2020 20:52:42 |

US3602123

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:13:32

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 02 May 2021 07:01:38 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 20:11:02 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 30 Apr 2021 11:44:18 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                     |                  |                      |
| User entered empty. | System           | 02 Oct 2020 20:52:42 |

US3602123

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:13:32

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 02 May 2021 07:01:38 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 20:11:02 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 30 Apr 2021 11:44:18 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                     |                  |                      |
| User entered empty. | System           | 02 Oct 2020 20:52:42 |

US3602123

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:13:32

[Condition](#)

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|  |                      |                      |
| Data hard unlocked.  | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|  |                      |                      |
| Data hard locked.  | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|  |                      |                      |
| Data hard unlocked.  | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|  |                      |                      |
| Data hard locked.  | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|  |                      |                      |
| User signature succeeded.  | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|  | (b) (4)              |                      |
| DataPoint Verified.  | (b) (4), (b) (6)     | 11 Mar 2021 15:33:07 |
|  |                      |                      |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Haematological and lymphoid tissue therapeutic procedures, HLT: Lymphoid tissue therapeutic procedures, PT: Splenectomy, LLT: Splenectomy - version MedDRA\\23.0. | Coder Import (b) (4) | 24 Nov 2020 17:54:01 |
|  | (b) (4)              |                      |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4) | 24 Nov 2020 17:54:01 |
|  | (b) (4)              |                      |
| Data point term sent to Coder  | System               | 24 Nov 2020 16:42:00 |
| User entered 'Splenectomy'   | (b) (4), (b) (6)     | 24 Nov 2020 16:41:34 |
|  |                      |                      |



US3602123

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:13:32

Start date (dd MMM yyyy)

| Audit                      | User                 | Time (GMT)           |
|----------------------------|----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                            |                      |                      |
| Data hard unlocked.        | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|                            |                      |                      |
| Data hard locked.          | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|                            |                      |                      |
| Data hard unlocked.        | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|                            |                      |                      |
| Data hard locked.          | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                            |                      |                      |
| User signature succeeded.  | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                            | (b) (4)              |                      |
| DataPoint Verified.        | (b) (4), (b) (6)     | 11 Mar 2021 15:33:07 |
|                            |                      |                      |
| User entered 'un UNK 2000' | (b) (4), (b) (6)     | 24 Nov 2020 16:41:34 |
|                            |                      |                      |

US3602123

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:13:32

Start date completely unknown

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| DataPoint Verified.       | (b) (4), (b) (6)     | 11 Mar 2021 15:33:07 |
|                           |                      |                      |
| User entered '0'          | (b) (4), (b) (6)     | 24 Nov 2020 16:41:34 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:13:32

[Condition ongoing at study entry](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| DataPoint Verified.       | (b) (4), (b) (6)     | 11 Mar 2021 15:33:07 |
|                           |                      |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)     | 24 Nov 2020 16:41:34 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:13:32

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

| Audit                      | User                 | Time (GMT)           |
|----------------------------|----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                            |                      |                      |
| Data hard unlocked.        | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|                            |                      |                      |
| Data hard locked.          | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|                            |                      |                      |
| Data hard unlocked.        | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|                            |                      |                      |
| Data hard locked.          | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                            |                      |                      |
| User signature succeeded.  | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                            | (b) (4)              |                      |
| DataPoint Verified.        | (b) (4), (b) (6)     | 11 Mar 2021 15:33:07 |
|                            |                      |                      |
| User entered 'un UNK 2000' | (b) (4), (b) (6)     | 24 Nov 2020 16:41:34 |
|                            |                      |                      |

US3602123

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:13:32

[Stop date completely unknown](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| DataPoint Verified.       | (b) (4), (b) (6)     | 11 Mar 2021 15:33:07 |
|                           |                      |                      |
| User entered '0'          | (b) (4), (b) (6)     | 24 Nov 2020 16:41:34 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:13:32

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                         |                  |                      |
| Data hard unlocked.     | (b) (4), (b) (6) | 02 May 2021 07:01:38 |
|                         |                  |                      |
| Data hard locked.       | (b) (4), (b) (6) | 01 May 2021 20:11:02 |
|                         |                  |                      |
| Data hard unlocked.     | (b) (4), (b) (6) | 30 Apr 2021 11:44:18 |
|                         |                  |                      |
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                         |                  |                      |
| User entered 'Jan 2000' | System           | 24 Nov 2020 16:41:34 |

US3602123

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:13:32

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 02 May 2021 07:01:38 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 20:11:02 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 30 Apr 2021 11:44:18 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                     |                  |                      |
| User entered '2000' | System           | 24 Nov 2020 16:41:34 |

US3602123

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:13:32

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                         |                  |                      |
| Data hard unlocked.     | (b) (4), (b) (6) | 02 May 2021 07:01:38 |
|                         |                  |                      |
| Data hard locked.       | (b) (4), (b) (6) | 01 May 2021 20:11:02 |
|                         |                  |                      |
| Data hard unlocked.     | (b) (4), (b) (6) | 30 Apr 2021 11:44:18 |
|                         |                  |                      |
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                         |                  |                      |
| User entered 'Jan 2000' | System           | 24 Nov 2020 16:41:34 |



US3602123

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:13:32

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 02 May 2021 07:01:38 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 20:11:02 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 30 Apr 2021 11:44:18 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                     |                  |                      |
| User entered '2000' | System           | 24 Nov 2020 16:41:34 |

US3602123

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:13:32

[Condition](#)

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|   |                      |                      |
| Data hard unlocked.   | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|   |                      |                      |
| Data hard locked.   | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|   |                      |                      |
| Data hard unlocked.   | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|   |                      |                      |
| Data hard locked.   | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|   |                      |                      |
| User signature succeeded.   | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|   | (b) (4)              |                      |
| DataPoint Verified.   | (b) (4), (b) (6)     | 11 Mar 2021 15:33:07 |
|   |                      |                      |
| User coded data point as SOC: Surgical and medical procedures, HLG: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: C-section - version MedDRA\\23.0. | Coder Import (b) (4) | 24 Nov 2020 17:55:06 |
|   | (b) (4)              |                      |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4) | 24 Nov 2020 17:55:06 |
|   | (b) (4)              |                      |
| Data point term sent to Coder   | System               | 24 Nov 2020 16:43:04 |
| User entered 'C-section'  | (b) (4), (b) (6)     | 24 Nov 2020 16:42:18 |
|   |                      |                      |

US3602123

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:13:32

Start date (dd MMM yyyy)

| Audit                      | User                 | Time (GMT)           |
|----------------------------|----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                            |                      |                      |
| Data hard unlocked.        | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|                            |                      |                      |
| Data hard locked.          | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|                            |                      |                      |
| Data hard unlocked.        | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|                            |                      |                      |
| Data hard locked.          | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                            |                      |                      |
| User signature succeeded.  | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                            | (b) (4)              |                      |
| DataPoint Verified.        | (b) (4), (b) (6)     | 11 Mar 2021 15:33:07 |
|                            |                      |                      |
| User entered 'un UNK 1999' | (b) (4), (b) (6)     | 24 Nov 2020 16:42:18 |
|                            |                      |                      |

US3602123

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:13:32

Start date completely unknown

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| DataPoint Verified.       | (b) (4), (b) (6)     | 11 Mar 2021 15:33:07 |
|                           |                      |                      |
| User entered '0'          | (b) (4), (b) (6)     | 24 Nov 2020 16:42:18 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:13:32

[Condition ongoing at study entry](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           | (b) (4), (b) (6)     |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|                           | (b) (4), (b) (6)     |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|                           | (b) (4), (b) (6)     |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|                           | (b) (4), (b) (6)     |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           | (b) (4), (b) (6)     |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| DataPoint Verified.       | (b) (4), (b) (6)     | 11 Mar 2021 15:33:07 |
|                           | (b) (4), (b) (6)     |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)     | 24 Nov 2020 16:42:18 |
|                           | (b) (4), (b) (6)     |                      |

US3602123

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:13:32

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

| Audit                      | User                 | Time (GMT)           |
|----------------------------|----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                            |                      |                      |
| Data hard unlocked.        | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|                            |                      |                      |
| Data hard locked.          | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|                            |                      |                      |
| Data hard unlocked.        | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|                            |                      |                      |
| Data hard locked.          | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                            |                      |                      |
| User signature succeeded.  | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                            | (b) (4)              |                      |
| DataPoint Verified.        | (b) (4), (b) (6)     | 11 Mar 2021 15:33:07 |
|                            |                      |                      |
| User entered 'un UNK 1999' | (b) (4), (b) (6)     | 24 Nov 2020 16:42:18 |
|                            |                      |                      |

US3602123

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:13:32

[Stop date completely unknown](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| DataPoint Verified.       | (b) (4), (b) (6)     | 11 Mar 2021 15:33:07 |
|                           |                      |                      |
| User entered '0'          | (b) (4), (b) (6)     | 24 Nov 2020 16:42:18 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:13:32

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                         |                  |                      |
| Data hard unlocked.     | (b) (4), (b) (6) | 02 May 2021 07:01:38 |
|                         |                  |                      |
| Data hard locked.       | (b) (4), (b) (6) | 01 May 2021 20:11:02 |
|                         |                  |                      |
| Data hard unlocked.     | (b) (4), (b) (6) | 30 Apr 2021 11:44:18 |
|                         |                  |                      |
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                         |                  |                      |
| User entered 'Jan 1999' | System           | 24 Nov 2020 16:42:18 |



US3602123

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:13:32

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 02 May 2021 07:01:38 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 20:11:02 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 30 Apr 2021 11:44:18 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                     |                  |                      |
| User entered '1999' | System           | 24 Nov 2020 16:42:18 |

US3602123

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:13:32

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                         |                  |                      |
| Data hard unlocked.     | (b) (4), (b) (6) | 02 May 2021 07:01:38 |
|                         |                  |                      |
| Data hard locked.       | (b) (4), (b) (6) | 01 May 2021 20:11:02 |
|                         |                  |                      |
| Data hard unlocked.     | (b) (4), (b) (6) | 30 Apr 2021 11:44:18 |
|                         |                  |                      |
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                         |                  |                      |
| User entered 'Jan 1999' | System           | 24 Nov 2020 16:42:18 |

US3602123

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:13:32

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 02 May 2021 07:01:38 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 20:11:02 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 30 Apr 2021 11:44:18 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                     |                  |                      |
| User entered '1999' | System           | 24 Nov 2020 16:42:18 |

US3602123

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:13:32

[Condition](#)

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|   |                      |                      |
| Data hard unlocked.   | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|   |                      |                      |
| Data hard locked.   | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|   |                      |                      |
| Data hard unlocked.   | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|   |                      |                      |
| Data hard locked.   | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|   |                      |                      |
| User signature succeeded.   | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|   | (b) (4)              |                      |
| DataPoint Verified.   | (b) (4), (b) (6)     | 11 Mar 2021 15:33:07 |
|   |                      |                      |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0. | Coder Import (b) (4) | 24 Nov 2020 17:55:06 |
|   | (b) (4)              |                      |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4) | 24 Nov 2020 17:55:06 |
|   | (b) (4)              |                      |
| Data point term sent to Coder   | System               | 24 Nov 2020 16:43:04 |
| User entered 'Cholycystectomy'  | (b) (4), (b) (6)     | 24 Nov 2020 16:42:59 |
|   |                      |                      |

US3602123

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:13:32

Start date (dd MMM yyyy)

| Audit                      | User                 | Time (GMT)           |
|----------------------------|----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                            |                      |                      |
| Data hard unlocked.        | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|                            |                      |                      |
| Data hard locked.          | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|                            |                      |                      |
| Data hard unlocked.        | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|                            |                      |                      |
| Data hard locked.          | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                            |                      |                      |
| User signature succeeded.  | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                            | (b) (4)              |                      |
| DataPoint Verified.        | (b) (4), (b) (6)     | 11 Mar 2021 15:33:07 |
|                            |                      |                      |
| User entered 'un UNK 2000' | (b) (4), (b) (6)     | 24 Nov 2020 16:42:59 |
|                            |                      |                      |

**US3602123**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:13:32**

[Start date completely unknown](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| DataPoint Verified.       | (b) (4), (b) (6)     | 11 Mar 2021 15:33:07 |
|                           |                      |                      |
| User entered '0'          | (b) (4), (b) (6)     | 24 Nov 2020 16:42:59 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:13:32

[Condition ongoing at study entry](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| DataPoint Verified.       | (b) (4), (b) (6)     | 11 Mar 2021 15:33:07 |
|                           |                      |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)     | 24 Nov 2020 16:42:59 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:13:32

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

| Audit                      | User                 | Time (GMT)           |
|----------------------------|----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                            |                      |                      |
| Data hard unlocked.        | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|                            |                      |                      |
| Data hard locked.          | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|                            |                      |                      |
| Data hard unlocked.        | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|                            |                      |                      |
| Data hard locked.          | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                            |                      |                      |
| User signature succeeded.  | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                            | (b) (4)              |                      |
| DataPoint Verified.        | (b) (4), (b) (6)     | 11 Mar 2021 15:33:07 |
|                            |                      |                      |
| User entered 'un UNK 2000' | (b) (4), (b) (6)     | 24 Nov 2020 16:42:59 |
|                            |                      |                      |



US3602123

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:13:32

[Stop date completely unknown](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| DataPoint Verified.       | (b) (4), (b) (6)     | 11 Mar 2021 15:33:07 |
|                           |                      |                      |
| User entered '0'          | (b) (4), (b) (6)     | 24 Nov 2020 16:42:59 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:13:32

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                         |                  |                      |
| Data hard unlocked.     | (b) (4), (b) (6) | 02 May 2021 07:01:38 |
|                         |                  |                      |
| Data hard locked.       | (b) (4), (b) (6) | 01 May 2021 20:11:02 |
|                         |                  |                      |
| Data hard unlocked.     | (b) (4), (b) (6) | 30 Apr 2021 11:44:18 |
|                         |                  |                      |
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                         |                  |                      |
| User entered 'Jan 2000' | System           | 24 Nov 2020 16:42:59 |

US3602123

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:13:32

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 02 May 2021 07:01:38 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 20:11:02 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 30 Apr 2021 11:44:18 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                     |                  |                      |
| User entered '2000' | System           | 24 Nov 2020 16:42:59 |

US3602123

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:13:32

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                         |                  |                      |
| Data hard unlocked.     | (b) (4), (b) (6) | 02 May 2021 07:01:38 |
|                         |                  |                      |
| Data hard locked.       | (b) (4), (b) (6) | 01 May 2021 20:11:02 |
|                         |                  |                      |
| Data hard unlocked.     | (b) (4), (b) (6) | 30 Apr 2021 11:44:18 |
|                         |                  |                      |
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                         |                  |                      |
| User entered 'Jan 2000' | System           | 24 Nov 2020 16:42:59 |

US3602123

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:13:32

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 02 May 2021 07:01:38 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 20:11:02 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 30 Apr 2021 11:44:18 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                     |                  |                      |
| User entered '2000' | System           | 24 Nov 2020 16:42:59 |

US3602123

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:13:32

[Condition](#)

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|  |                      |                      |
| Data hard unlocked.  | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|  |                      |                      |
| Data hard locked.  | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|  |                      |                      |
| Data hard unlocked.  | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|  |                      |                      |
| Data hard locked.  | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|  |                      |                      |
| User signature succeeded.  | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|  | (b) (4)              |                      |
| DataPoint Verified.  | (b) (4), (b) (6)     | 11 Mar 2021 15:33:07 |
|  |                      |                      |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Breast therapeutic procedures, HLT: Breast therapeutic procedures NEC, PT: Mammoplasty, LLT: Augmentation mammoplasty - version MedDRA\\23.0. | Coder Import (b) (4) | 24 Nov 2020 17:23:03 |
|  | (b) (4)              |                      |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4) | 24 Nov 2020 17:23:03 |
|  | (b) (4)              |                      |
| Data point term sent to Coder  | System               | 24 Nov 2020 16:57:21 |
| User entered 'Breast Augmentation'   | (b) (4), (b) (6)     | 24 Nov 2020 16:56:29 |
|  |                      |                      |

US3602123

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:13:32

Start date (dd MMM yyyy)

| Audit                      | User                 | Time (GMT)           |
|----------------------------|----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                            |                      |                      |
| Data hard unlocked.        | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|                            |                      |                      |
| Data hard locked.          | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|                            |                      |                      |
| Data hard unlocked.        | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|                            |                      |                      |
| Data hard locked.          | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                            |                      |                      |
| User signature succeeded.  | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                            | (b) (4)              |                      |
| DataPoint Verified.        | (b) (4), (b) (6)     | 11 Mar 2021 15:33:07 |
|                            |                      |                      |
| User entered 'un UNK 2020' | (b) (4), (b) (6)     | 24 Nov 2020 16:56:29 |
|                            |                      |                      |

US3602123

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:13:32

Start date completely unknown

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| DataPoint Verified.       | (b) (4), (b) (6)     | 11 Mar 2021 15:33:07 |
|                           |                      |                      |
| User entered '0'          | (b) (4), (b) (6)     | 24 Nov 2020 16:56:29 |
|                           |                      |                      |



US3602123

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:13:32

[Condition ongoing at study entry](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| DataPoint Verified.       | (b) (4), (b) (6)     | 11 Mar 2021 15:33:07 |
|                           |                      |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)     | 24 Nov 2020 16:56:29 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:13:32

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

| Audit                      | User                 | Time (GMT)           |
|----------------------------|----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                            |                      |                      |
| Data hard unlocked.        | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|                            |                      |                      |
| Data hard locked.          | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|                            |                      |                      |
| Data hard unlocked.        | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|                            |                      |                      |
| Data hard locked.          | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                            |                      |                      |
| User signature succeeded.  | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                            | (b) (4)              |                      |
| DataPoint Verified.        | (b) (4), (b) (6)     | 11 Mar 2021 15:33:07 |
|                            |                      |                      |
| User entered 'un UNK 2020' | (b) (4), (b) (6)     | 24 Nov 2020 16:56:29 |
|                            |                      |                      |

US3602123

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:13:32

[Stop date completely unknown](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| DataPoint Verified.       | (b) (4), (b) (6)     | 11 Mar 2021 15:33:07 |
|                           |                      |                      |
| User entered '0'          | (b) (4), (b) (6)     | 24 Nov 2020 16:56:29 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:13:32

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                         |                  |                      |
| Data hard unlocked.     | (b) (4), (b) (6) | 02 May 2021 07:01:38 |
|                         |                  |                      |
| Data hard locked.       | (b) (4), (b) (6) | 01 May 2021 20:11:02 |
|                         |                  |                      |
| Data hard unlocked.     | (b) (4), (b) (6) | 30 Apr 2021 11:44:18 |
|                         |                  |                      |
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                         |                  |                      |
| User entered 'Jan 2020' | System           | 24 Nov 2020 16:56:29 |

US3602123

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:13:32

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 02 May 2021 07:01:38 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 20:11:02 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 30 Apr 2021 11:44:18 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                     |                  |                      |
| User entered '2020' | System           | 24 Nov 2020 16:56:29 |

US3602123

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:13:32

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                         |                  |                      |
| Data hard unlocked.     | (b) (4), (b) (6) | 02 May 2021 07:01:38 |
|                         |                  |                      |
| Data hard locked.       | (b) (4), (b) (6) | 01 May 2021 20:11:02 |
|                         |                  |                      |
| Data hard unlocked.     | (b) (4), (b) (6) | 30 Apr 2021 11:44:18 |
|                         |                  |                      |
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                         |                  |                      |
| User entered 'Jan 2020' | System           | 24 Nov 2020 16:56:29 |

US3602123

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:13:32

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 02 May 2021 07:01:38 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 20:11:02 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 30 Apr 2021 11:44:18 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                     |                  |                      |
| User entered '2020' | System           | 24 Nov 2020 16:56:29 |

US3602123

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:13:32

[Condition](#)

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|  |                      |                      |
| Data hard unlocked.  | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|  |                      |                      |
| Data hard locked.  | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|  |                      |                      |
| Data hard unlocked.  | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|  |                      |                      |
| Data hard locked.  | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|  |                      |                      |
| User signature succeeded.  | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|  | (b) (4)              |                      |
| DataPoint Verified.  | (b) (4), (b) (6)     | 11 Mar 2021 15:33:07 |
|  |                      |                      |
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0. | Coder Import (b) (4) | 01 Dec 2020 16:14:59 |
|  | (b) (4)              |                      |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4) | 01 Dec 2020 16:14:59 |
|  | (b) (4)              |                      |
| Data point term sent to Coder  | System               | 01 Dec 2020 16:13:45 |
| User entered 'Seasonal Allergies'  | (b) (4), (b) (6)     | 01 Dec 2020 16:13:05 |
|  |                      |                      |



**US3602123**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:13:32**

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

| Audit                      | User                 | Time (GMT)           |
|----------------------------|----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                            |                      |                      |
| Data hard unlocked.        | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|                            |                      |                      |
| Data hard locked.          | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|                            |                      |                      |
| Data hard unlocked.        | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|                            |                      |                      |
| Data hard locked.          | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                            |                      |                      |
| User signature succeeded.  | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                            | (b) (4)              |                      |
| DataPoint Verified.        | (b) (4), (b) (6)     | 11 Mar 2021 15:33:07 |
|                            |                      |                      |
| User entered 'un UNK 2018' | (b) (4), (b) (6)     | 01 Dec 2020 16:13:05 |
|                            |                      |                      |

US3602123

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:13:32

Start date completely unknown

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| DataPoint Verified.       | (b) (4), (b) (6)     | 11 Mar 2021 15:33:07 |
|                           |                      |                      |
| User entered '0'          | (b) (4), (b) (6)     | 01 Dec 2020 16:13:05 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:13:32

[Condition ongoing at study entry](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| DataPoint Verified.       | (b) (4), (b) (6)     | 11 Mar 2021 15:33:07 |
|                           |                      |                      |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)     | 01 Dec 2020 16:13:05 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:13:32

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

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| DataPoint Verified.       | (b) (4), (b) (6)     | 11 Mar 2021 15:33:07 |
|                           |                      |                      |
| User entered empty.       | (b) (4), (b) (6)     | 01 Dec 2020 16:13:05 |
|                           |                      |                      |

**US3602123**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:13:32**

[Stop date completely unknown](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| DataPoint Verified.       | (b) (4), (b) (6)     | 11 Mar 2021 15:33:07 |
|                           |                      |                      |
| User entered '0'          | (b) (4), (b) (6)     | 01 Dec 2020 16:13:05 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:13:32

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                         |                  |                      |
| Data hard unlocked.     | (b) (4), (b) (6) | 02 May 2021 07:01:38 |
|                         |                  |                      |
| Data hard locked.       | (b) (4), (b) (6) | 01 May 2021 20:11:02 |
|                         |                  |                      |
| Data hard unlocked.     | (b) (4), (b) (6) | 30 Apr 2021 11:44:18 |
|                         |                  |                      |
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                         |                  |                      |
| User entered 'Jan 2018' | System           | 01 Dec 2020 16:13:05 |

US3602123

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:13:32

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 02 May 2021 07:01:38 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 20:11:02 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 30 Apr 2021 11:44:18 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                     |                  |                      |
| User entered '2018' | System           | 01 Dec 2020 16:13:05 |

US3602123

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:13:32

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 02 May 2021 07:01:38 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 20:11:02 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 30 Apr 2021 11:44:18 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                     |                  |                      |
| User entered empty. | System           | 01 Dec 2020 16:13:05 |



US3602123

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:13:32

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 02 May 2021 07:01:38 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 20:11:02 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 30 Apr 2021 11:44:18 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                     |                  |                      |
| User entered empty. | System           | 01 Dec 2020 16:13:05 |

US3602123

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:13:32

Condition

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
| Data hard unlocked.   | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
| User signature succeeded.   | Bindu Balani (b) (4) | 02 May 2021 01:32:35 |
| Data hard locked.   | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
| Data hard unlocked.   | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
| Data hard locked.   | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
| User coded data point as SOC: Investigations, HLGT: Metabolic, nutritional and blood gas investigations, HLT: Vitamin analyses, PT: Vitamin D decreased, LLT: Vitamin D low - version MedDRA\\23.0. | Coder Import (b) (4) | 27 Apr 2021 15:30:14 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.   | Coder Import (b) (4) | 27 Apr 2021 15:30:14 |
| Data point term sent to Coder   | System               | 27 Apr 2021 14:24:35 |
| User entered 'Borderline low vitamin D deficiency'  | (b) (4), (b) (6)     | 27 Apr 2021 14:24:29 |
| DataPoint activated with code reason code Data required.  | (b) (4), (b) (6)     | 27 Apr 2021 14:23:13 |
| DataPoint inactivated with code reason code Data not required.  | (b) (4), (b) (6)     | 18 Feb 2021 20:15:36 |

US3602123

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:13:32

Start date (dd MMM yyyy)

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|  |                      |                      |
| Data hard unlocked.  | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|  |                      |                      |
| User signature succeeded.                                      | Bindu Balani (b) (4) | 02 May 2021 01:32:35 |
|  | (b) (4)              |                      |
| Data hard locked.  | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|  |                      |                      |
| Data hard unlocked.  | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|  |                      |                      |
| Data hard locked.  | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|  |                      |                      |
| User entered 'un UNK 2018'                                     | (b) (4), (b) (6)     | 27 Apr 2021 14:24:29 |
|  |                      |                      |
| DataPoint activated with code reason code Data required.       | (b) (4), (b) (6)     | 27 Apr 2021 14:23:13 |
|  |                      |                      |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)     | 18 Feb 2021 20:15:36 |
|  |                      |                      |

US3602123

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:13:32

Start date completely unknown

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|  |                      |                      |
| Data hard unlocked.  | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|  |                      |                      |
| User signature succeeded.                                      | Bindu Balani (b) (4) | 02 May 2021 01:32:35 |
|  | (b) (4)              |                      |
| Data hard locked.  | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|  |                      |                      |
| Data hard unlocked.  | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|  |                      |                      |
| Data hard locked.  | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|  |                      |                      |
| User entered '0'   | (b) (4), (b) (6)     | 27 Apr 2021 14:24:29 |
|  |                      |                      |
| DataPoint activated with code reason code Data required.       | (b) (4), (b) (6)     | 27 Apr 2021 14:23:13 |
|  |                      |                      |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)     | 18 Feb 2021 20:15:36 |
|  |                      |                      |

US3602123

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:13:32

[Condition ongoing at study entry](#)

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|  | (b) (4), (b) (6)     |                      |
| Data hard unlocked.  | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|  | (b) (4), (b) (6)     |                      |
| User signature succeeded.                                      | Bindu Balani (b) (4) | 02 May 2021 01:32:35 |
|  | (b) (4)              |                      |
| Data hard locked.  | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|  | (b) (4), (b) (6)     |                      |
| Data hard unlocked.  | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|  | (b) (4), (b) (6)     |                      |
| Data hard locked.  | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|  | (b) (4), (b) (6)     |                      |
| User entered 'Yes (Y)'   | (b) (4), (b) (6)     | 27 Apr 2021 14:24:29 |
|  | (b) (4), (b) (6)     |                      |
| DataPoint activated with code reason code Data required.       | (b) (4), (b) (6)     | 27 Apr 2021 14:23:13 |
|  | (b) (4), (b) (6)     |                      |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)     | 18 Feb 2021 20:15:36 |
|  | (b) (4), (b) (6)     |                      |

US3602123

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:13:32

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

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|  |                      |                      |
| Data hard unlocked.  | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|  |                      |                      |
| User signature succeeded.                                      | Bindu Balani (b) (4) | 02 May 2021 01:32:35 |
|  | (b) (4)              |                      |
| Data hard locked.  | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|  |                      |                      |
| Data hard unlocked.  | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|  |                      |                      |
| Data hard locked.  | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|  |                      |                      |
| User entered empty.  | (b) (4), (b) (6)     | 27 Apr 2021 14:24:29 |
|  |                      |                      |
| DataPoint activated with code reason code Data required.       | (b) (4), (b) (6)     | 27 Apr 2021 14:23:13 |
|  |                      |                      |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)     | 18 Feb 2021 20:15:36 |
|  |                      |                      |

US3602123

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:13:32

[Stop date completely unknown](#)

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|  | (b) (4), (b) (6)     |                      |
| Data hard unlocked.  | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|  | (b) (4), (b) (6)     |                      |
| User signature succeeded.                                      | Bindu Balani (b) (4) | 02 May 2021 01:32:35 |
|  | (b) (4)              |                      |
| Data hard locked.  | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|  | (b) (4), (b) (6)     |                      |
| Data hard unlocked.  | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|  | (b) (4), (b) (6)     |                      |
| Data hard locked.  | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|  | (b) (4), (b) (6)     |                      |
| User entered '0'   | (b) (4), (b) (6)     | 27 Apr 2021 14:24:29 |
|  | (b) (4), (b) (6)     |                      |
| DataPoint activated with code reason code Data required.       | (b) (4), (b) (6)     | 27 Apr 2021 14:23:13 |
|  | (b) (4), (b) (6)     |                      |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)     | 18 Feb 2021 20:15:36 |
|  | (b) (4), (b) (6)     |                      |

US3602123

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:13:32

Start Month and Year (derived)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|  |                  |                      |
| Data hard unlocked.  | (b) (4), (b) (6) | 02 May 2021 07:01:38 |
|  |                  |                      |
| Data hard locked.  | (b) (4), (b) (6) | 01 May 2021 20:11:02 |
|  |                  |                      |
| Data hard unlocked.  | (b) (4), (b) (6) | 30 Apr 2021 11:44:18 |
|  |                  |                      |
| Data hard locked.  | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|  |                  |                      |
| User entered 'Jan 2018'  | System           | 27 Apr 2021 14:24:29 |
| DataPoint activated with code reason code Data required.       | (b) (4), (b) (6) | 27 Apr 2021 14:23:13 |
|  |                  |                      |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6) | 18 Feb 2021 20:15:36 |
|  |                  |                      |



US3602123

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:13:32

Start Year (derived)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|  |                  |                      |
| Data hard unlocked.  | (b) (4), (b) (6) | 02 May 2021 07:01:38 |
|  |                  |                      |
| Data hard locked.  | (b) (4), (b) (6) | 01 May 2021 20:11:02 |
|  |                  |                      |
| Data hard unlocked.  | (b) (4), (b) (6) | 30 Apr 2021 11:44:18 |
|  |                  |                      |
| Data hard locked.  | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|  |                  |                      |
| User entered '2018'  | System           | 27 Apr 2021 14:24:29 |
| DataPoint activated with code reason code Data required.       | (b) (4), (b) (6) | 27 Apr 2021 14:23:13 |
|  |                  |                      |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6) | 18 Feb 2021 20:15:36 |
|  |                  |                      |

US3602123

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:13:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|  |                  |                      |
| Data hard unlocked.  | (b) (4), (b) (6) | 02 May 2021 07:01:38 |
|  |                  |                      |
| Data hard locked.  | (b) (4), (b) (6) | 01 May 2021 20:11:02 |
|  |                  |                      |
| Data hard unlocked.  | (b) (4), (b) (6) | 30 Apr 2021 11:44:18 |
|  |                  |                      |
| Data hard locked.  | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|  |                  |                      |
| User entered empty.  | System           | 27 Apr 2021 14:24:29 |
| DataPoint activated with code reason code Data required.       | (b) (4), (b) (6) | 27 Apr 2021 14:23:13 |
|  |                  |                      |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6) | 18 Feb 2021 20:15:36 |
|  |                  |                      |

US3602123

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:13:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|  |                  |                      |
| Data hard unlocked.  | (b) (4), (b) (6) | 02 May 2021 07:01:38 |
|  |                  |                      |
| Data hard locked.  | (b) (4), (b) (6) | 01 May 2021 20:11:02 |
|  |                  |                      |
| Data hard unlocked.  | (b) (4), (b) (6) | 30 Apr 2021 11:44:18 |
|  |                  |                      |
| Data hard locked.  | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|  |                  |                      |
| User entered empty.  | System           | 27 Apr 2021 14:24:29 |
| DataPoint activated with code reason code Data required.       | (b) (4), (b) (6) | 27 Apr 2021 14:23:13 |
|  |                  |                      |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6) | 18 Feb 2021 20:15:36 |
|  |                  |                      |

US3602123

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:13:32

Condition

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|   |                      |                      |
| Data hard unlocked.   | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|   |                      |                      |
| User signature succeeded.   | Bindu Balani (b) (4) | 02 May 2021 01:32:35 |
|   | (b) (4)              |                      |
| Data hard locked.   | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|   |                      |                      |
| Data hard unlocked.   | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|   |                      |                      |
| Data hard locked.   | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|   |                      |                      |
| User coded data point as SOC: Investigations,<br>HLGT: Lipid analyses, HLT: Cholesterol analyses,<br>PT: Blood cholesterol increased, LLT: Cholesterol<br>high - version MedDRA\23.0. | Coder Import (b) (4) | 27 Apr 2021 14:27:59 |
|   | (b) (4)              |                      |
| User coded data point as Term Coded data point by<br>User: Coder System - version MedDRA\23.0.  | Coder Import (b) (4) | 27 Apr 2021 14:27:59 |
|   | (b) (4)              |                      |
| Data point term sent to Coder<br>System   |                      | 27 Apr 2021 14:26:39 |
| User entered 'Borderline high cholesterol '   | (b) (4), (b) (6)     | 27 Apr 2021 14:25:49 |
|   |                      |                      |

**US3602123**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:13:32**

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

| Audit                      | User                 | Time (GMT)           |
|----------------------------|----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                            |                      |                      |
| Data hard unlocked.        | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|                            |                      |                      |
| User signature succeeded.  | Bindu Balani (b) (4) | 02 May 2021 01:32:35 |
|                            | (b) (4)              |                      |
| Data hard locked.          | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|                            |                      |                      |
| Data hard unlocked.        | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|                            |                      |                      |
| Data hard locked.          | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                            |                      |                      |
| User entered 'un UNK 2018' | (b) (4), (b) (6)     | 27 Apr 2021 14:25:49 |
|                            |                      |                      |

**US3602123**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:13:32**

[Start date completely unknown](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 02 May 2021 01:32:35 |
|                           | (b) (4)              |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User entered '0'          | (b) (4), (b) (6)     | 27 Apr 2021 14:25:49 |
|                           |                      |                      |

**US3602123**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:13:32**

[Condition ongoing at study entry](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 02 May 2021 01:32:35 |
|                           | (b) (4)              |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)     | 27 Apr 2021 14:25:49 |
|                           |                      |                      |

**US3602123**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:13:32**

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

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 02 May 2021 01:32:35 |
|                           | (b) (4)              |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User entered empty.       | (b) (4), (b) (6)     | 27 Apr 2021 14:25:49 |
|                           |                      |                      |



**US3602123**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:13:32**

[Stop date completely unknown](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:38 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 02 May 2021 01:32:35 |
|                           | (b) (4)              |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 01 May 2021 20:11:02 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 30 Apr 2021 11:44:18 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User entered '0'          | (b) (4), (b) (6)     | 27 Apr 2021 14:25:49 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:13:32

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                         |                  |                      |
| Data hard unlocked.     | (b) (4), (b) (6) | 02 May 2021 07:01:38 |
|                         |                  |                      |
| Data hard locked.       | (b) (4), (b) (6) | 01 May 2021 20:11:02 |
|                         |                  |                      |
| Data hard unlocked.     | (b) (4), (b) (6) | 30 Apr 2021 11:44:18 |
|                         |                  |                      |
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                         |                  |                      |
| User entered 'Jan 2018' | System           | 27 Apr 2021 14:25:49 |

US3602123

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:13:32

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 02 May 2021 07:01:38 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 20:11:02 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 30 Apr 2021 11:44:18 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                     |                  |                      |
| User entered '2018' | System           | 27 Apr 2021 14:25:49 |

US3602123

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:13:32

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 02 May 2021 07:01:38 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 20:11:02 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 30 Apr 2021 11:44:18 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                     |                  |                      |
| User entered empty. | System           | 27 Apr 2021 14:25:49 |

US3602123

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:13:32

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 02 May 2021 07:01:38 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 20:11:02 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 30 Apr 2021 11:44:18 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                     |                  |                      |
| User entered empty. | System           | 27 Apr 2021 14:25:49 |

US3602123

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:32

[Were vital signs assessed?](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:46 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)     | 02 Oct 2020 20:47:40 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:32

Date of assessment (*dd MMM yyyy*)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:46 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered '2 Oct 2020' | (b) (4), (b) (6)     | 02 Oct 2020 20:47:40 |
|                           |                      |                      |

**US3602123**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[Time of assessment \(00:00-23:59\)](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:46 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered '13:16'      | (b) (4), (b) (6)     | 02 Oct 2020 20:47:40 |
|                           |                      |                      |



US3602123

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:32

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

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                                 |                  |                      |
| Data hard unlocked.             | (b) (4), (b) (6) | 02 May 2021 07:01:46 |
|                                 |                  |                      |
| Data hard locked.               | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                                 |                  |                      |
| User entered '2 Oct 2020 13:16' | System           | 02 Oct 2020 20:47:40 |

US3602123

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:32

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

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:46 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered '65' in      | (b) (4), (b) (6)     | 02 Oct 2020 20:47:40 |
|                           |                      |                      |
| DataPoint set to visible. | System               | 02 Oct 2020 19:46:12 |

US3602123

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:32

Weight (xxx.x)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:46 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered '151' lb     | (b) (4), (b) (6)     | 02 Oct 2020 20:47:40 |
|                           |                      |                      |
| DataPoint set to visible. | System               | 02 Oct 2020 19:46:12 |

US3602123

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:32

BMI (xxx.x)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                           |                  |                      |
| Data hard unlocked.       | (b) (4), (b) (6) | 02 May 2021 07:01:46 |
|                           |                  |                      |
| Data hard locked.         | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                           |                  |                      |
| User entered '25.18025'   | System           | 02 Oct 2020 20:47:40 |
| DataPoint set to visible. | System           | 02 Oct 2020 19:46:12 |

**US3602123**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[BMI units](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                           |                  |                      |
| Data hard unlocked.       | (b) (4), (b) (6) | 02 May 2021 07:01:46 |
|                           |                  |                      |
| Data hard locked.         | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                           |                  |                      |
| User entered 'kg/m2'      | System           | 02 Oct 2020 20:47:40 |
| DataPoint set to visible. | System           | 02 Oct 2020 19:46:12 |

US3602123

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:32

Temperature (xxx.x)

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| Data hard locked.                                   | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|   |                      |                      |
| Data hard unlocked.                                 | (b) (4), (b) (6)     | 02 May 2021 07:01:46 |
|   |                      |                      |
| Data hard locked.                                   | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|   |                      |                      |
| User signature succeeded.                           | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|   | (b) (4)              |                      |
| User entered missing code ND - Not Done; reason for | (b) (4), (b) (6)     | 07 Oct 2020 19:24:28 |
| change Data Entry Error                             |                      |                      |
| User entered '97.8' F                               | (b) (4), (b) (6)     | 02 Oct 2020 20:47:40 |
|   |                      |                      |

US3602123

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:32

[Route of measurement](#)

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|  |                      |                      |
| Data hard unlocked.                                    | (b) (4), (b) (6)     | 02 May 2021 07:01:46 |
|  |                      |                      |
| Data hard locked.                                      | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|  |                      |                      |
| User signature succeeded.                              | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|  | (b) (4)              |                      |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6)     | 07 Oct 2020 19:24:28 |
|  |                      |                      |
| User entered 'Other (Other)'                           | (b) (4), (b) (6)     | 02 Oct 2020 20:47:40 |
|  |                      |                      |

US3602123

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:32

[If Other, specify](#)

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|  |                      |                      |
| Data hard unlocked.                                    | (b) (4), (b) (6)     | 02 May 2021 07:01:46 |
|  |                      |                      |
| Data hard locked.                                      | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|  |                      |                      |
| User signature succeeded.                              | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|  | (b) (4)              |                      |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6)     | 07 Oct 2020 19:24:28 |
|  |                      |                      |
| User entered 'Temporal/Forehead scanner used'          | (b) (4), (b) (6)     | 02 Oct 2020 20:47:40 |
|  |                      |                      |



US3602123

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:32

[Pulse \(xxx\)](#)

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
| Data hard unlocked.  | (b) (4), (b) (6)     | 02 May 2021 07:01:46 |
| Data hard locked.  | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
| User signature succeeded.  | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
| User closed query 'Per CDM: Re-query: Response noted however, this is not the required response. according to CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND - 'Not Done' should be recorded for PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. and Please consider to keep the corresponding 'Units' blank. update appropriately. Thank you.' (Site from DM).                       | (b) (4), (b) (6)     | 12 Oct 2020 12:52:24 |
| Query 'Per CDM: Re-query: Response noted however, this is not the required response. according to CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND - 'Not Done' should be recorded for PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. and Please consider to keep the corresponding 'Units' blank. update appropriately. Thank you.' answered with 'Updated per query' (Site from DM). | (b) (4), (b) (6)     | 09 Oct 2020 20:46:08 |
| User entered missing code ND - Not Done; reason for change Data Entry Error  | (b) (4), (b) (6)     | 09 Oct 2020 20:46:04 |
| User opened query 'Per CDM: Re-query: Response noted however, this is not the required response. according to CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND - 'Not Done' should be recorded for PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. and Please consider to keep the corresponding 'Units' blank. update appropriately. Thank you.' (Site from DM).                       | (b) (4), (b) (6)     | 09 Oct 2020 14:38:28 |
| User closed query 'Data is required. Please provide.' (Site from System).  | (b) (4), (b) (6)     | 09 Oct 2020 14:38:07 |

US3602123

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:32

[Pulse \(xxx\)](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Query 'Data is required. Please provide.' answered with 'Field is to remain 'blank' per query' (Site from System). | (b) (4), (b) (6) | 08 Oct 2020 22:59:49 |
| User opened query 'Data is required. Please provide.' System (Site from System).                                   |                  | 08 Oct 2020 22:59:47 |
| User entered empty; reason for change Data Entry Error   | (b) (4), (b) (6) | 08 Oct 2020 22:59:47 |
| User entered missing code ND - Not Done; reason for change Data Entry Error  | (b) (4), (b) (6) | 07 Oct 2020 19:24:28 |
| User entered '86'  | (b) (4), (b) (6) | 02 Oct 2020 20:47:40 |

**US3602123**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[Pulse units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 02 May 2021 07:01:46 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                     |                  |                      |
| User entered 'bpm'  | System           | 09 Oct 2020 20:46:04 |
| User entered empty. | System           | 08 Oct 2020 22:59:47 |
| User entered 'bpm'  | System           | 02 Oct 2020 20:47:40 |

US3602123

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:32

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

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|  |                      |                      |
| Data hard unlocked.  | (b) (4), (b) (6)     | 02 May 2021 07:01:46 |
|  |                      |                      |
| Data hard locked.  | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|  |                      |                      |
| User signature succeeded.  | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|  | (b) (4)              |                      |
| User entered missing code ND - Not Done; reason for change Data Entry Error  | (b) (4), (b) (6)     | 09 Oct 2020 20:46:04 |
|  |                      |                      |
| User closed query 'Data is required. Please provide.' (Site from System).  | (b) (4), (b) (6)     | 09 Oct 2020 14:38:33 |
|  |                      |                      |
| Query 'Data is required. Please provide.' answered with 'Field is to remain 'blank' per query' (Site from System). | (b) (4), (b) (6)     | 08 Oct 2020 22:59:52 |
|  |                      |                      |
| User opened query 'Data is required. Please provide.' System (Site from System).                                   |                      | 08 Oct 2020 22:59:47 |
|  |                      |                      |
| User entered empty; reason for change Data Entry Error   | (b) (4), (b) (6)     | 08 Oct 2020 22:59:47 |
|  |                      |                      |
| User entered missing code ND - Not Done; reason for change Data Entry Error  | (b) (4), (b) (6)     | 07 Oct 2020 19:24:28 |
|  |                      |                      |
| User entered '18'  | (b) (4), (b) (6)     | 02 Oct 2020 20:47:40 |
|  |                      |                      |

US3602123

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:32

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                            |                  |                      |
| Data hard unlocked.        | (b) (4), (b) (6) | 02 May 2021 07:01:46 |
|                            |                  |                      |
| Data hard locked.          | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                            |                  |                      |
| User entered 'breaths/min' | System           | 09 Oct 2020 20:46:04 |
| User entered empty.        | System           | 08 Oct 2020 22:59:47 |
| User entered 'breaths/min' | System           | 02 Oct 2020 20:47:40 |

US3602123

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:32

Systolic Blood Pressure (xxx)

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|  |                      |                      |
| Data hard unlocked.  | (b) (4), (b) (6)     | 02 May 2021 07:01:46 |
|  |                      |                      |
| Data hard locked.  | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|  |                      |                      |
| User signature succeeded.  | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|  | (b) (4)              |                      |
| User entered missing code ND - Not Done; reason for change Data Entry Error  | (b) (4), (b) (6)     | 09 Oct 2020 20:46:04 |
|  |                      |                      |
| User closed query 'Data is required. Please provide.' (Site from System).  | (b) (4), (b) (6)     | 09 Oct 2020 14:38:35 |
|  |                      |                      |
| Query 'Data is required. Please provide.' answered with 'Field is to remain 'blank' per query' (Site from System). | (b) (4), (b) (6)     | 08 Oct 2020 22:59:54 |
|  |                      |                      |
| User opened query 'Data is required. Please provide.' System (Site from System).                                   |                      | 08 Oct 2020 22:59:47 |
|  |                      |                      |
| User entered empty; reason for change Data Entry Error   | (b) (4), (b) (6)     | 08 Oct 2020 22:59:47 |
|  |                      |                      |
| User entered missing code ND - Not Done; reason for change Data Entry Error  | (b) (4), (b) (6)     | 07 Oct 2020 19:24:28 |
|  |                      |                      |
| User entered '139'   | (b) (4), (b) (6)     | 02 Oct 2020 20:47:40 |
|  |                      |                      |

US3602123

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:32

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 02 May 2021 07:01:46 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                     |                  |                      |
| User entered 'mmHg' | System           | 09 Oct 2020 20:46:04 |
| User entered empty. | System           | 08 Oct 2020 22:59:47 |
| User entered 'mmHg' | System           | 02 Oct 2020 20:47:40 |

US3602123

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:32

Diastolic Blood Pressure (xxx)

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
| Data hard unlocked.  | (b) (4), (b) (6)     | 02 May 2021 07:01:46 |
| Data hard locked.  | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
| User signature succeeded.  | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
| User entered missing code ND - Not Done; reason for change Data Entry Error  | (b) (4), (b) (6)     | 09 Oct 2020 20:46:04 |
| User closed query 'Data is required. Please provide.' (Site from System).  | (b) (4), (b) (6)     | 09 Oct 2020 14:38:38 |
| Query 'Data is required. Please provide.' answered with 'Field is to remain 'blank' per query' (Site from System). | (b) (4), (b) (6)     | 08 Oct 2020 22:59:56 |
| User opened query 'Data is required. Please provide.' System (Site from System).                                   |                      | 08 Oct 2020 22:59:47 |
| User entered empty; reason for change Data Entry Error   | (b) (4), (b) (6)     | 08 Oct 2020 22:59:47 |
| User entered missing code ND - Not Done; reason for change Data Entry Error  | (b) (4), (b) (6)     | 07 Oct 2020 19:24:28 |
| User entered '88'  | (b) (4), (b) (6)     | 02 Oct 2020 20:47:40 |



US3602123

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:32

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 02 May 2021 07:01:46 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                     |                  |                      |
| User entered 'mmHg' | System           | 09 Oct 2020 20:46:04 |
| User entered empty. | System           | 08 Oct 2020 22:59:47 |
| User entered 'mmHg' | System           | 02 Oct 2020 20:47:40 |

**US3602123**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[Height \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 02 May 2021 07:01:46 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                     |                  |                      |

US3602123

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:32

Weight (derived)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 02 May 2021 07:01:46 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                     |                  |                      |

US3602123

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:13:32

[Was the physical examination performed?](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:51 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)     | 02 Oct 2020 20:42:57 |
|                           |                      |                      |

**US3602123**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:13:32**

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

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:51 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered '2 Oct 2020' | (b) (4), (b) (6)     | 02 Oct 2020 20:42:57 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:13:32

Date of assessment (*dd MMM yyyy*)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:56 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered '2 Oct 2020' | (b) (4), (b) (6)     | 02 Oct 2020 20:44:34 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:13:32

[Is the participant of childbearing potential?](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:56 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)     | 02 Oct 2020 20:44:34 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:13:32

[If No, what is the reason?](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:56 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered empty.       | (b) (4), (b) (6)     | 02 Oct 2020 20:44:34 |
|                           |                      |                      |



US3602123

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:13:32

If Partner medically sterile or Other, specify

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:56 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered empty.       | (b) (4), (b) (6)     | 02 Oct 2020 20:44:34 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:13:32

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

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:56 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered empty.       | (b) (4), (b) (6)     | 02 Oct 2020 20:44:34 |
|                           |                      |                      |

**US3602123**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:13:32**

[Date of surgery unknown](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:56 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered '0'          | (b) (4), (b) (6)     | 02 Oct 2020 20:44:34 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:13:32

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

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:56 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered empty.       | (b) (4), (b) (6)     | 02 Oct 2020 20:44:34 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:13:32

[Date of last menstruation unknown](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:01:56 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered '0'          | (b) (4), (b) (6)     | 02 Oct 2020 20:44:34 |
|                           |                      |                      |

**US3602123**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:13:32**

[Was the pregnancy test performed?](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:02:01 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)     | 02 Oct 2020 20:45:03 |
|                           |                      |                      |

**US3602123**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:13:32**

**Date of test (dd MMM yyyy)**

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:02:01 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered '2 Oct 2020' | (b) (4), (b) (6)     | 02 Oct 2020 20:45:03 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:13:32

[Test performed](#)

| Audit                        | User                 | Time (GMT)           |
|------------------------------|----------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                              |                      |                      |
| Data hard unlocked.          | (b) (4), (b) (6)     | 02 May 2021 07:02:01 |
|                              |                      |                      |
| Data hard locked.            | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                              |                      |                      |
| User signature succeeded.    | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                              | (b) (4)              |                      |
| User entered 'Urine (URINE)' | (b) (4), (b) (6)     | 02 Oct 2020 20:45:03 |
|                              |                      |                      |



**US3602123**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:13:32**

[Result](#)

| Audit                              | User                 | Time (GMT)           |
|------------------------------------|----------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                                    |                      |                      |
| Data hard unlocked.                | (b) (4), (b) (6)     | 02 May 2021 07:02:01 |
|                                    |                      |                      |
| Data hard locked.                  | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                                    |                      |                      |
| User signature succeeded.          | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                                    | (b) (4)              |                      |
| User entered 'Negative (NEGATIVE)' | (b) (4), (b) (6)     | 02 Oct 2020 20:45:03 |
|                                    |                      |                      |

**US3602123**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:13:32**

[Was FSH sample collected?](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:02:01 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)     | 02 Oct 2020 20:45:03 |
|                           |                      |                      |

**US3602123**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:13:32**

[Collection date](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:02:01 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered empty.       | (b) (4), (b) (6)     | 02 Oct 2020 20:45:03 |
|                           |                      |                      |

**US3602123**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:13:32**

[Collection time](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:02:01 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered empty.       | (b) (4), (b) (6)     | 02 Oct 2020 20:45:03 |
|                           |                      |                      |

**US3602123**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:13:32**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 22:51:27 |
|                     |                  |                      |
| Data hard unlocked. | (b) (4), (b) (6) | 02 May 2021 07:02:01 |
|                     |                  |                      |
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 06:34:02 |
|                     |                  |                      |
| User entered empty. | System           | 02 Oct 2020 20:45:03 |

US3602123

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:32

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:02:06 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)     | 02 Oct 2020 20:43:34 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:32

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:02:06 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)     | 02 Oct 2020 20:43:34 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:32

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:02:06 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)     | 02 Oct 2020 20:43:34 |
|                           |                      |                      |



US3602123

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:32

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:02:06 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)     | 02 Oct 2020 20:43:34 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:32

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:02:06 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)     | 02 Oct 2020 20:43:34 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:32

**Transportation and delivery services** (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:02:06 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)     | 02 Oct 2020 20:43:34 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:32

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:02:06 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)     | 02 Oct 2020 20:43:34 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:32

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:02:06 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)     | 02 Oct 2020 20:43:34 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:32

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:02:06 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)     | 02 Oct 2020 20:43:34 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:32

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:02:06 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)     | 02 Oct 2020 20:43:34 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:32

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:02:06 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)     | 02 Oct 2020 20:43:34 |
|                           |                      |                      |



**US3602123**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:13:32**

**Other**

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:02:06 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)     | 02 Oct 2020 20:43:34 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:32

[Specify](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:02:06 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered empty.       | (b) (4), (b) (6)     | 02 Oct 2020 20:43:34 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:32

No Risk Identified

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:02:06 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered 'I'          | (b) (4), (b) (6)     | 02 Oct 2020 20:43:34 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:32

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

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:02:06 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered '0'          | (b) (4), (b) (6)     | 02 Oct 2020 20:43:34 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:32

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:02:06 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered '0'          | (b) (4), (b) (6)     | 02 Oct 2020 20:43:34 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:32

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:02:06 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered '0'          | (b) (4), (b) (6)     | 02 Oct 2020 20:43:34 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:32

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:02:06 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered '0'          | (b) (4), (b) (6)     | 02 Oct 2020 20:43:34 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:32

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

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:02:06 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered '0'          | (b) (4), (b) (6)     | 02 Oct 2020 20:43:34 |
|                           |                      |                      |



US3602123

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:32

[Other](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:02:06 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered '0'          | (b) (4), (b) (6)     | 02 Oct 2020 20:43:34 |
|                           |                      |                      |

US3602123

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:13:32

[Specify](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 02 May 2021 22:51:27 |
|                           |                      |                      |
| Data hard unlocked.       | (b) (4), (b) (6)     | 02 May 2021 07:02:06 |
|                           |                      |                      |
| Data hard locked.         | (b) (4), (b) (6)     | 28 Apr 2021 06:34:02 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered empty.       | (b) (4), (b) (6)     | 02 Oct 2020 20:43:34 |
|                           |                      |                      |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:32**

[Was this visit performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:50:03 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:32**

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '2 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:50:03 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:32**

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

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.      | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:50:03 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:32**

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered 'VISIT1' | System           | 02 Oct 2020 20:50:03 |

US3602123

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:13:32

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

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 14 Apr 2021 12:26:08 |
| User signature succeeded.  | Bindu Balani (b) (4)                        | 05 Apr 2021 21:30:07 |
| User entered '02 OCT 2020' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 02 Oct 2020 17:52:43 |

US3602123

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:13:32

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

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)                        | 05 Apr 2021 21:30:07 |
| User entered '116294'     | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 02 Oct 2020 17:52:43 |



US3602123

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:13:32

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

| Audit   | User  | Time (GMT)           |
|---|---|----------------------|
| Data hard locked.                                     | (b) (4), (b) (6)                            | 14 Apr 2021 12:26:08 |
| User signature succeeded.                             | Bindu Balani (b) (4)                        | 05 Apr 2021 21:30:07 |
| User entered '>=18 and <65 years and not at risk (1)' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 02 Oct 2020 17:52:43 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:13:32**

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:50:27 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:13:32**

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:50:27 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:13:32**

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:50:27 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:13:32**

[Diabetes \(Type I, Type 2, or gestational\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:50:27 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:13:32**

[Liver Disease](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:50:27 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:13:32**

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:50:27 |
| DataPoint set to visible. | System                      | 02 Oct 2020 19:45:43 |

US3602123

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:13:32

Height

| Audit                                    | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.                | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered missing code ND - Not Done. | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:49:28 |



**US3602123**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:13:32**

[Weight](#)

| Audit                                    | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.                | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered missing code ND - Not Done. | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:49:28 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:13:32**

[Height](#)

| Audit                                    | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.                | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered missing code ND - Not Done. | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:49:28 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:13:32**

[Weight](#)

| Audit                                    | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.                | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered missing code ND - Not Done. | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:49:28 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Timepoint](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.                                | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User accepted default value 'Pre-Dose (PREDOSE)' | (b) (4), (b) (6) | 02 Oct 2020 20:49:28 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Were vital signs assessed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:49:28 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

**Date of assessment** (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '2 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:49:28 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '13:16'      | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:49:28 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

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

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered '2 Oct 2020 13:16' | System           | 02 Oct 2020 20:49:28 |



US3602123

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:32

Temperature (xxx.x)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '97.8' F     | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:49:28 |

US3602123

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:32

[Route of measurement](#)

| Audit                        | User                        | Time (GMT)           |
|------------------------------|-----------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.    | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Other (Other)' | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:49:28 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[If Other, specify](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.                             | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.                     | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Temporal/Forehead scanner used' | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:49:28 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Pulse \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '86'         | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:49:28 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered 'bpm' | System           | 02 Oct 2020 20:49:28 |

US3602123

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:32

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '18'         | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:49:28 |

US3602123

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:32

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered 'breaths/min' | System           | 02 Oct 2020 20:49:28 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '139'        | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:49:28 |



**US3602123**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered 'mmHg' | System           | 02 Oct 2020 20:49:28 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '88'         | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:49:28 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered 'mmHg' | System           | 02 Oct 2020 20:49:28 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:13:32**

[Height](#)

| Audit                                    | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.                | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered missing code ND - Not Done. | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:49:28 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:13:32**

[Weight](#)

| Audit                                    | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.                | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered missing code ND - Not Done. | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:49:28 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Timepoint](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User accepted default value 'Post-Dose (POSTDOSE)' | (b) (4), (b) (6) | 02 Oct 2020 20:49:28 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Were vital signs assessed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:49:28 |

US3602123

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:32

Date of assessment (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '2 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:49:28 |



**US3602123**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '16:02'      | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:49:28 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

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

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered '2 Oct 2020 16:02' | System           | 02 Oct 2020 20:49:28 |

US3602123

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:32

Temperature (xxx.x)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '97.6' F     | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:49:28 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Route of measurement](#)

| Audit                        | User                        | Time (GMT)           |
|------------------------------|-----------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.    | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Other (Other)' | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:49:28 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[If Other, specify](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.                             | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.                     | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Temporal/Forehead scanner used' | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:49:28 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Pulse \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '80'         | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:49:28 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered 'bpm' | System           | 02 Oct 2020 20:49:28 |

US3602123

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:32

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '18'         | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:49:28 |



US3602123

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:32

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered 'breaths/min' | System           | 02 Oct 2020 20:49:28 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '143'        | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:49:28 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered 'mmHg' | System           | 02 Oct 2020 20:49:28 |

US3602123

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:32

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '68'         | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:49:28 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered 'mmHg' | System           | 02 Oct 2020 20:49:28 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:13:32**

[Was the physical examination performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:49:35 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:13:32**

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:49:35 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:13:32**

[Was the pregnancy test performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:49:51 |



**US3602123**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:13:32**

**Date of test** (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:49:51 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:13:32**

[Test performed](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:49:51 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:13:32**

[Result](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:49:51 |

US3602123

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:13:32

[Was FSH sample collected?](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User closed query 'Per CDM: Please consider entering "No" for this field as screening and VID1 have occurred on the same day.' (Site from DM).             | (b) (4)<br>(b) (4), (b) (6) | 09 Oct 2020 06:17:23 |
| Query 'Per CDM: Please consider entering "No" for this field as screening and VID1 have occurred on the same day.' answered with 'Updated' (Site from DM). | (b) (4), (b) (6)            | 08 Oct 2020 23:07:38 |
| User entered 'No (N)' reason for change: Data Entry Error  | (b) (4), (b) (6)            | 08 Oct 2020 23:07:32 |
| User opened query 'Per CDM: Please consider entering "No" for this field as screening and VID1 have occurred on the same day.' (Site from DM).             | (b) (4), (b) (6)            | 07 Oct 2020 12:18:38 |
| User entered empty.  | (b) (4), (b) (6)            | 02 Oct 2020 20:49:51 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:13:32**

[Collection date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:49:51 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:13:32**

[Collection time](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:49:51 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:13:32**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered empty. | System           | 02 Oct 2020 20:49:51 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:32**

[Was study treatment given?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 19:46:47 |



**US3602123**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:32**

[If No, reason not given](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 19:46:47 |

US3602123

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:13:32

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:32**

[What was the study treatment?](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| Data hard locked.                   | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered 'MRNA-1273 OR PLACEBO' | System           | 02 Oct 2020 19:46:47 |

US3602123

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:13:32

What was the treatment date? (dd MMM yyyy)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '2 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:32**

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '15:32'      | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:32**

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

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered '2 Oct 2020 15:32' | System           | 02 Oct 2020 19:46:47 |

US3602123

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:13:32

[Which arm was used to give treatment?](#)

| Audit                              | User                        | Time (GMT)           |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.          | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 19:46:47 |

US3602123

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:13:32

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered 'ONCE' | System           | 02 Oct 2020 19:46:47 |



**US3602123**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:32**

[What was the route of administration for the study treatment?](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered 'INTRAMUSCULAR' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:32**

[Was the sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:50:41 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:32**

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '2 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:50:41 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:32**

[Collection time \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '13:16'      | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:50:41 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:32**

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

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered '2 Oct 2020 13:16' | System           | 02 Oct 2020 20:50:41 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 09:13:32**

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '2 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:51:03 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Lab Test](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | (b) (4), (b) (6) | 02 Oct 2020 20:51:03 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Was the sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:51:03 |



**US3602123**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Collection time \(00:00 - 23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '13:43'      | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:51:03 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:13:32**

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

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered '2 Oct 2020 13:43' | System           | 02 Oct 2020 20:51:03 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Lab Test](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | (b) (4), (b) (6) | 02 Oct 2020 20:51:03 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Was the sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:51:03 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Collection time \(00:00 - 23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:51:03 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:13:32**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered empty. | System           | 02 Oct 2020 20:51:03 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:32**

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 02 Oct 2020 20:51:19 |

**US3602123**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:32**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered 'I'  | System           | 02 Oct 2020 20:51:19 |



**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 02 Oct 2020 19:46:47 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:32**

**Was TEMPERATURE taken?**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-02T16:10:51', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'b4e04989-7d6a-448d-8378-ccfda7552d3c' User entered 'Yes (Y)' | System           | 02 Oct 2020 20:11:10 |
|   | System           | 02 Oct 2020 20:11:10 |

US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:13:32

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-02T16:10:57', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'b4e04989-7d6a-448d-8378-ccfda7552d3c' User entered '97.6' | System           | 02 Oct 2020 20:11:10 |
|  | System           | 02 Oct 2020 20:11:10 |

US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:13:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-02T16:11:02', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'b4e04989-7d6a-448d-8378-ccfda7552d3c' User entered 'No (N)' | System           | 02 Oct 2020 20:11:10 |
|  | System           | 02 Oct 2020 20:11:10 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-02T16:11:07', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'b4e04989-7d6a-448d-8378-ccfda7552d3c' User entered '02 Oct 2020 16:11' | System           | 02 Oct 2020 20:11:10 |
|   | System           | 02 Oct 2020 20:11:10 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '02 Oct 2020 15:52' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '02 Oct 2020 18:22' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.                                | System           | 02 Oct 2020 19:46:47 |
| User entered 'Day 1, after vaccination (at home)' | System           | 02 Oct 2020 19:46:47 |



**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:32**

**Was TEMPERATURE taken?**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-02T20:46:14', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'e1ddb3b0-bc52-45fd-ae03-41f0e33d965a' User entered 'Yes (Y)' | System           | 03 Oct 2020 00:46:27 |
|   | System           | 03 Oct 2020 00:46:27 |

US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:13:32

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-02T20:46:19', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'e1ddb3b0-bc52-45fd-ae03-41f0e33d965a' User entered '98.7' | System           | 03 Oct 2020 00:46:27 |
|  | System           | 03 Oct 2020 00:46:27 |

US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:13:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-02T20:46:22', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'e1ddb3b0-bc52-45fd-ae03-41f0e33d965a' User entered 'No (N)' | System           | 03 Oct 2020 00:46:27 |
|  | System           | 03 Oct 2020 00:46:27 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-02T20:46:26', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'e1ddb3b0-bc52-45fd-ae03-41f0e33d965a' User entered '02 Oct 2020 20:46' | System           | 03 Oct 2020 00:46:27 |
|   | System           | 03 Oct 2020 00:46:27 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '02 Oct 2020 19:17' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '03 Oct 2020 11:59' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 02 Oct 2020 19:46:47 |
| User entered 'Day 2' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:13:32**

**Was TEMPERATURE taken?**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-03T19:15:48', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'aaa5b883-84f4-4e7d-899f-53014af13ed2' User entered 'Yes (Y)' | System           | 03 Oct 2020 23:16:01 |
|   | System           | 03 Oct 2020 23:16:01 |



US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:13:32

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-03T19:15:52', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'aaa5b883-84f4-4e7d-899f-53014af13ed2' User entered '97.7' | System           | 03 Oct 2020 23:16:01 |
|  | System           | 03 Oct 2020 23:16:01 |

US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:13:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-03T19:15:55', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'aaa5b883-84f4-4e7d-899f-53014af13ed2' | System           | 03 Oct 2020 23:16:01 |
| User entered 'No (N)'  | System           | 03 Oct 2020 23:16:01 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-03T19:16:00', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'aaa5b883-84f4-4e7d-899f-53014af13ed2' | System           | 03 Oct 2020 23:16:01 |
| User entered '03 Oct 2020 19:16'   | System           | 03 Oct 2020 23:16:01 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '03 Oct 2020 12:00' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '04 Oct 2020 11:59' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 02 Oct 2020 19:46:47 |
| User entered 'Day 3' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:13:32**

**Was TEMPERATURE taken?**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-04T12:32:52', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '910755af-8e55-4fa4-a902-a94f705888d6' User entered 'Yes (Y)' | System           | 04 Oct 2020 16:33:05 |
|   | System           | 04 Oct 2020 16:33:05 |

US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:13:32

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-04T12:32:57', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '910755af-8e55-4fa4-a902-a94f705888d6' User entered '97.8' | System           | 04 Oct 2020 16:33:05 |
|  | System           | 04 Oct 2020 16:33:05 |



US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:13:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-04T12:33:00', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '910755af-8e55-4fa4-a902-a94f705888d6' | System           | 04 Oct 2020 16:33:05 |
| User entered 'No (N)'  | System           | 04 Oct 2020 16:33:05 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-04T12:33:02', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '910755af-8e55-4fa4-a902-a94f705888d6' User entered '04 Oct 2020 12:33' | System           | 04 Oct 2020 16:33:05 |
|   | System           | 04 Oct 2020 16:33:05 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '04 Oct 2020 12:00' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '05 Oct 2020 11:59' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 02 Oct 2020 19:46:47 |
| User entered 'Day 4' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:13:32**

**Was TEMPERATURE taken?**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-05T18:23:36', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '64074bcd-f210-4075-8eb6-19ccb4af5e26' User entered 'Yes (Y)' | System           | 05 Oct 2020 22:23:49 |
|   | System           | 05 Oct 2020 22:23:49 |

US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:13:32

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-05T18:23:41', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '64074bcd-f210-4075-8eb6-19ccb4af5e26' User entered '99.2' | System           | 05 Oct 2020 22:23:49 |
|  | System           | 05 Oct 2020 22:23:49 |

US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:13:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-05T18:23:44', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '64074bcd-f210-4075-8eb6-19ccb4af5e26' | System           | 05 Oct 2020 22:23:49 |
| User entered 'No (N)'  | System           | 05 Oct 2020 22:23:49 |



**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-05T18:23:48', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '64074bcd-f210-4075-8eb6-19ccb4af5e26' User entered '05 Oct 2020 18:23' | System           | 05 Oct 2020 22:23:49 |
|   | System           | 05 Oct 2020 22:23:49 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '05 Oct 2020 12:00' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '06 Oct 2020 11:59' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 02 Oct 2020 19:46:47 |
| User entered 'Day 5' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:13:32**

**Was TEMPERATURE taken?**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-06T18:26:28', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '74173291-ac8b-47cb-b206-2dda5f9eef7a' User entered 'Yes (Y)' | System           | 06 Oct 2020 22:26:54 |
|   | System           | 06 Oct 2020 22:26:54 |

US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:13:32

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-06T18:26:31', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '74173291-ac8b-47cb-b206-2dda5f9eef7a' User entered '99.1' | System           | 06 Oct 2020 22:26:54 |
|  | System           | 06 Oct 2020 22:26:54 |

US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:13:32

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

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-06T18:26:35', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '74173291-ac8b-47cb-b206-2dda5f9eef7a' User entered 'Yes (Y)' | System           | 06 Oct 2020 22:26:54 |
|   | System           | 06 Oct 2020 22:26:54 |

US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:13:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| 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 'Follow-up Safety call will be made on Day 8 to get more info' (Site from System). | (b) (4), (b) (6) | 13 Oct 2020 04:06:26 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).   | (b) (4), (b) (6) | 08 Oct 2020 23:09:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-06T18:26:47', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '74173291-ac8b-47cb-b206-2dda5f9eef7a'   | System           | 06 Oct 2020 22:26:54 |
| User entered '1'   | System           | 06 Oct 2020 22:26:54 |



US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:13:32

To **PREVENT** pain or fever from occurring

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-06T18:26:47', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '74173291-ac8b-47cb-b206-2dda5f9eef7a' User entered '0' | System           | 06 Oct 2020 22:26:54 |
|   | System           | 06 Oct 2020 22:26:54 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-06T18:26:52', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '74173291-ac8b-47cb-b206-2dda5f9eef7a' User entered '06 Oct 2020 18:26' | System           | 06 Oct 2020 22:26:54 |
|   | System           | 06 Oct 2020 22:26:54 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '06 Oct 2020 12:00' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '07 Oct 2020 11:59' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 02 Oct 2020 19:46:47 |
| User entered 'Day 6' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:13:32**

**Was TEMPERATURE taken?**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-07T14:34:21', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '4b3c5379-9124-4d60-951f-ce67e3118d76' User entered 'Yes (Y)' | System           | 07 Oct 2020 18:34:36 |
|   | System           | 07 Oct 2020 18:34:36 |

US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:13:32

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-07T14:34:27', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '4b3c5379-9124-4d60-951f-ce67e3118d76' User entered '97.8' | System           | 07 Oct 2020 18:34:36 |
|  | System           | 07 Oct 2020 18:34:36 |

US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:13:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-07T14:34:29', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '4b3c5379-9124-4d60-951f-ce67e3118d76' User entered 'No (N)' | System           | 07 Oct 2020 18:34:36 |
|  | System           | 07 Oct 2020 18:34:36 |



**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-07T14:34:34', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '4b3c5379-9124-4d60-951f-ce67e3118d76' User entered '07 Oct 2020 14:34' | System           | 07 Oct 2020 18:34:36 |
|   | System           | 07 Oct 2020 18:34:36 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '07 Oct 2020 12:00' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '08 Oct 2020 11:59' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 02 Oct 2020 19:46:47 |
| User entered 'Day 7' | System           | 02 Oct 2020 19:46:47 |

US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:13:32

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-08T19:51:00', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '6b50aa74-2631-4f6d-8e71-3829f0f51ee9' User entered 'Yes (Y)' | System           | 08 Oct 2020 23:51:23 |
|   | System           | 08 Oct 2020 23:51:23 |

US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:13:32

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-08T19:51:04', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '6b50aa74-2631-4f6d-8e71-3829f0f51ee9' User entered '98.5' | System           | 08 Oct 2020 23:51:23 |
|  | System           | 08 Oct 2020 23:51:23 |

US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:13:32

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

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-08T19:51:12', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '6b50aa74-2631-4f6d-8e71-3829f0f51ee9' User entered 'Yes (Y)' | System           | 08 Oct 2020 23:51:23 |
|   | System           | 08 Oct 2020 23:51:23 |

US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:13:32

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

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| 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 'Medication confirmed and inserted in Con meds' (Site from System). | (b) (4), (b) (6) | 06 Nov 2020 05:52:00 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).  | (b) (4), (b) (6) | 05 Nov 2020 18:16:24 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-08T19:51:18', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '6b50aa74-2631-4f6d-8e71-3829f0f51ee9'  | System           | 08 Oct 2020 23:51:23 |
| User entered '1'  | System           | 08 Oct 2020 23:51:23 |



US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:13:32

To **PREVENT** pain or fever from occurring

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-08T19:51:18', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '6b50aa74-2631-4f6d-8e71-3829f0f51ee9' User entered '0' | System           | 08 Oct 2020 23:51:23 |
|   | System           | 08 Oct 2020 23:51:23 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-08T19:51:21', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '6b50aa74-2631-4f6d-8e71-3829f0f51ee9' User entered '08 Oct 2020 19:51' | System           | 08 Oct 2020 23:51:23 |
|   | System           | 08 Oct 2020 23:51:23 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '08 Oct 2020 12:00' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '09 Oct 2020 11:59' | System           | 02 Oct 2020 19:46:47 |

US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 08 Oct 2020 23:51:23 |
| User entered 'Day 8' | System           | 08 Oct 2020 23:51:23 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(8)**

**Generated On: 10 Jun 2021 09:13:32**

**Was TEMPERATURE taken?**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-09T20:53:18', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'ac48e049-bac9-4816-8d15-539113c37ecb' User entered 'Yes (Y)' | System           | 10 Oct 2020 00:53:38 |
|   | System           | 10 Oct 2020 00:53:38 |

US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 09:13:32

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-09T20:53:26', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'ac48e049-bac9-4816-8d15-539113c37ecb' User entered '98.2' | System           | 10 Oct 2020 00:53:38 |
|  | System           | 10 Oct 2020 00:53:38 |

US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 09:13:32

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

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-09T20:53:30', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'ac48e049-bac9-4816-8d15-539113c37ecb' User entered 'Yes (Y)' | System           | 10 Oct 2020 00:53:38 |
|   | System           | 10 Oct 2020 00:53:38 |



US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 09:13:32

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

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| 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 'Medications updated in Con meds' (Site from System). | (b) (4), (b) (6) | 06 Nov 2020 05:52:22 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-09T20:53:34', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'ac48e049-bac9-4816-8d15-539113c37ecb' User entered '1'                    | (b) (4), (b) (6) | 05 Nov 2020 18:17:24 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).  | System           | 10 Oct 2020 00:53:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-09T20:53:34', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'ac48e049-bac9-4816-8d15-539113c37ecb' User entered '1'   | System           | 10 Oct 2020 00:53:38 |
| User entered '1'  | System           | 10 Oct 2020 00:53:38 |

US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 09:13:32

To **PREVENT** pain or fever from occurring

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-09T20:53:34', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'ac48e049-bac9-4816-8d15-539113c37ecb' User entered '0' | System           | 10 Oct 2020 00:53:38 |
|   | System           | 10 Oct 2020 00:53:38 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(8)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-09T20:53:37', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'ac48e049-bac9-4816-8d15-539113c37ecb' User entered '09 Oct 2020 20:53' | System           | 10 Oct 2020 00:53:38 |
|   | System           | 10 Oct 2020 00:53:38 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(8)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '09 Oct 2020 12:00' | System           | 08 Oct 2020 23:51:23 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(8)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '10 Oct 2020 11:59' | System           | 08 Oct 2020 23:51:23 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(9)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 08 Oct 2020 23:51:23 |
| User entered 'Day 9' | System           | 08 Oct 2020 23:51:23 |

US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 09:13:32

Was **TEMPERATURE** taken?

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
|                   |                  |                      |

US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 09:13:32

Please record your **TEMPERATURE** in °F

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
|                   |                  |                      |



US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 09:13:32

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
|                   |                  |                      |

US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 09:13:32

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
|                   |                  |                      |

US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 09:13:32

To **PREVENT** pain or fever from occurring

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
|                   |                  |                      |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(9)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time Stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
|                   |                  |                      |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(9)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '10 Oct 2020 12:00' | System           | 08 Oct 2020 23:51:23 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(9)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '11 Oct 2020 11:59' | System           | 08 Oct 2020 23:51:23 |

US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 10 Jun 2021 09:13:32

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.    | System           | 10 Oct 2020 00:53:38 |
| User entered 'Day 10' | System           | 10 Oct 2020 00:53:38 |

US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 10 Jun 2021 09:13:32

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-11T13:42:11', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'ee9fa3bc-b17e-489e-a55f-688612291244' User entered 'Yes (Y)' | System           | 11 Oct 2020 17:42:24 |
|   | System           | 11 Oct 2020 17:42:24 |



US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 10 Jun 2021 09:13:32

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-11T13:42:15', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'ee9fa3bc-b17e-489e-a55f-688612291244' User entered '97.9' | System           | 11 Oct 2020 17:42:24 |
|  | System           | 11 Oct 2020 17:42:24 |

US3602123

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 10 Jun 2021 09:13:32

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-11T13:42:18', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'ee9fa3bc-b17e-489e-a55f-688612291244' | System           | 11 Oct 2020 17:42:24 |
| User entered 'No (N)'  | System           | 11 Oct 2020 17:42:24 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(10)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-11T13:42:21', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'ee9fa3bc-b17e-489e-a55f-688612291244' | System           | 11 Oct 2020 17:42:24 |
| User entered '11 Oct 2020 13:42'   | System           | 11 Oct 2020 17:42:24 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(10)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '11 Oct 2020 12:00' | System           | 10 Oct 2020 00:53:38 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(10)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '12 Oct 2020 11:59' | System           | 10 Oct 2020 00:53:38 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 02 Oct 2020 19:46:47 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 02 Oct 2020 19:46:47 |

US3602123

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:32

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-02T16:12:03', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '016dc614-dc73-46a8-889e-36bedd98890e' User entered 'None (1)' | System           | 02 Oct 2020 20:12:33 |
|  | System           | 02 Oct 2020 20:12:33 |

US3602123

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:32

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-02T16:12:07', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '016dc614-dc73-46a8-889e-36bedd98890e' User entered 'No (N)' | System           | 02 Oct 2020 20:12:33 |
|  | System           | 02 Oct 2020 20:12:33 |



US3602123

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:32

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-02T16:12:20', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '016dc614-dc73-46a8-889e-36bedd98890e' User entered 'No (N)' | System           | 02 Oct 2020 20:12:33 |
|  | System           | 02 Oct 2020 20:12:33 |

US3602123

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:32

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-02T16:12:25', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '016dc614-dc73-46a8-889e-36bedd98890e' User entered 'None (1)' | System           | 02 Oct 2020 20:12:33 |
|  | System           | 02 Oct 2020 20:12:33 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-02T16:12:29', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '016dc614-dc73-46a8-889e-36bedd98890e' User entered '02 Oct 2020 16:12' | System           | 02 Oct 2020 20:12:33 |
|   | System           | 02 Oct 2020 20:12:33 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '02 Oct 2020 15:52' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '02 Oct 2020 18:22' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.                                | System           | 02 Oct 2020 19:46:47 |
| User entered 'Day 1, after vaccination (at home)' | System           | 02 Oct 2020 19:46:47 |

US3602123

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:32

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-02T20:46:34', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '0e0f658d-53ef-41aa-9c8b-53c749b6c9ef' User entered 'None (1)' | System           | 03 Oct 2020 00:46:46 |
|  | System           | 03 Oct 2020 00:46:46 |

US3602123

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:32

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-02T20:46:37', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '0e0f658d-53ef-41aa-9c8b-53c749b6c9ef' User entered 'No (N)' | System           | 03 Oct 2020 00:46:46 |
|  | System           | 03 Oct 2020 00:46:46 |



US3602123

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:32

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-02T20:46:39', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '0e0f658d-53ef-41aa-9c8b-53c749b6c9ef' User entered 'No (N)' | System           | 03 Oct 2020 00:46:46 |
|  | System           | 03 Oct 2020 00:46:46 |

US3602123

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:32

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-02T20:46:42', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '0e0f658d-53ef-41aa-9c8b-53c749b6c9ef' User entered 'None (1)' | System           | 03 Oct 2020 00:46:46 |
|  | System           | 03 Oct 2020 00:46:46 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-02T20:46:45', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '0e0f658d-53ef-41aa-9c8b-53c749b6c9ef' User entered '02 Oct 2020 20:46' | System           | 03 Oct 2020 00:46:46 |
|   | System           | 03 Oct 2020 00:46:46 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '02 Oct 2020 19:17' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '03 Oct 2020 11:59' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 02 Oct 2020 19:46:47 |
| User entered 'Day 2' | System           | 02 Oct 2020 19:46:47 |

US3602123

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:32

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-03T19:16:04', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'aaa3ad6c-b8c8-4866-9392-ab7eccc30a40' User entered 'None (1)' | System           | 03 Oct 2020 23:16:20 |
|  | System           | 03 Oct 2020 23:16:20 |

US3602123

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:32

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-03T19:16:07', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'aaa3ad6c-b8c8-4866-9392-ab7eccc30a40' User entered 'No (N)' | System           | 03 Oct 2020 23:16:20 |
|  | System           | 03 Oct 2020 23:16:20 |



US3602123

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:32

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-03T19:16:10', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'aaa3ad6c-b8c8-4866-9392-ab7eccc30a40' User entered 'No (N)' | System           | 03 Oct 2020 23:16:20 |
|  | System           | 03 Oct 2020 23:16:20 |

US3602123

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:32

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-03T19:16:13', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'aaa3ad6c-b8c8-4866-9392-ab7eccc30a40' User entered 'None (1)' | System           | 03 Oct 2020 23:16:20 |
|  | System           | 03 Oct 2020 23:16:20 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-03T19:16:17', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'aaa3ad6c-b8c8-4866-9392-ab7eccc30a40' User entered '03 Oct 2020 19:16' | System           | 03 Oct 2020 23:16:20 |
|   | System           | 03 Oct 2020 23:16:20 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '03 Oct 2020 12:00' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '04 Oct 2020 11:59' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 02 Oct 2020 19:46:47 |
| User entered 'Day 3' | System           | 02 Oct 2020 19:46:47 |

US3602123

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:32

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-04T12:32:18', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'b92d03f0-8429-4492-9e9f-4135097b594f' User entered 'None (1)' | System           | 04 Oct 2020 16:32:29 |
|  | System           | 04 Oct 2020 16:32:29 |

US3602123

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:32

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-04T12:32:21', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'b92d03f0-8429-4492-9e9f-4135097b594f' User entered 'No (N)' | System           | 04 Oct 2020 16:32:29 |
|  | System           | 04 Oct 2020 16:32:29 |



US3602123

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:32

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-04T12:32:23', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'b92d03f0-8429-4492-9e9f-4135097b594f' User entered 'No (N)' | System           | 04 Oct 2020 16:32:29 |
|  | System           | 04 Oct 2020 16:32:29 |

US3602123

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:32

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-04T12:32:25', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'b92d03f0-8429-4492-9e9f-4135097b594f' User entered 'None (1)' | System           | 04 Oct 2020 16:32:29 |
|  | System           | 04 Oct 2020 16:32:29 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-04T12:32:27', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'b92d03f0-8429-4492-9e9f-4135097b594f' User entered '04 Oct 2020 12:32' | System           | 04 Oct 2020 16:32:29 |
|   | System           | 04 Oct 2020 16:32:29 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '04 Oct 2020 12:00' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '05 Oct 2020 11:59' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 02 Oct 2020 19:46:47 |
| User entered 'Day 4' | System           | 02 Oct 2020 19:46:47 |

US3602123

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:32

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-05T18:23:51', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '03ba277e-580f-4fac-a39e-809dfc8ac2ee' | System           | 05 Oct 2020 22:24:16 |
| User entered 'None (1)'  | System           | 05 Oct 2020 22:24:16 |

US3602123

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:32

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-05T18:23:57', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '03ba277e-580f-4fac-a39e-809dfc8ac2ee' User entered 'No (N)' | System           | 05 Oct 2020 22:24:16 |
|  | System           | 05 Oct 2020 22:24:16 |



US3602123

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:32

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-05T18:24:09', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '03ba277e-580f-4fac-a39e-809dfc8ac2ee' User entered 'No (N)' | System           | 05 Oct 2020 22:24:16 |
|  | System           | 05 Oct 2020 22:24:16 |

US3602123

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:32

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-05T18:24:12', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '03ba277e-580f-4fac-a39e-809dfc8ac2ee' User entered 'None (1)' | System           | 05 Oct 2020 22:24:16 |
|  | System           | 05 Oct 2020 22:24:16 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-05T18:24:14', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '03ba277e-580f-4fac-a39e-809dfc8ac2ee' User entered '05 Oct 2020 18:24' | System           | 05 Oct 2020 22:24:16 |
|   | System           | 05 Oct 2020 22:24:16 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '05 Oct 2020 12:00' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '06 Oct 2020 11:59' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 02 Oct 2020 19:46:47 |
| User entered 'Day 5' | System           | 02 Oct 2020 19:46:47 |

US3602123

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:32

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-06T18:26:55', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'fc5574c0-7a06-415a-accf-1b0543245639' User entered 'None (1)' | System           | 06 Oct 2020 22:27:08 |
|  | System           | 06 Oct 2020 22:27:08 |

US3602123

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:32

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-06T18:26:57', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'fc5574c0-7a06-415a-accf-1b0543245639' User entered 'No (N)' | System           | 06 Oct 2020 22:27:08 |
|  | System           | 06 Oct 2020 22:27:08 |



US3602123

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:32

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-06T18:27:00', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'fc5574c0-7a06-415a-accf-1b0543245639' User entered 'No (N)' | System           | 06 Oct 2020 22:27:08 |
|  | System           | 06 Oct 2020 22:27:08 |

US3602123

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:32

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-06T18:27:01', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'fc5574c0-7a06-415a-accf-1b0543245639' User entered 'None (1)' | System           | 06 Oct 2020 22:27:08 |
|  | System           | 06 Oct 2020 22:27:08 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-06T18:27:03', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'fc5574c0-7a06-415a-accf-1b0543245639' User entered '06 Oct 2020 18:27' | System           | 06 Oct 2020 22:27:08 |
|   | System           | 06 Oct 2020 22:27:08 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '06 Oct 2020 12:00' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '07 Oct 2020 11:59' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 02 Oct 2020 19:46:47 |
| User entered 'Day 6' | System           | 02 Oct 2020 19:46:47 |

US3602123

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:32

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-07T14:34:37', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'c18d5f27-e549-4207-9f64-4ff0e473c726' | System           | 07 Oct 2020 18:34:47 |
| User entered 'None (1)'  | System           | 07 Oct 2020 18:34:47 |

US3602123

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:32

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-07T14:34:39', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'c18d5f27-e549-4207-9f64-4ff0e473c726' | System           | 07 Oct 2020 18:34:47 |
| User entered 'No (N)'  | System           | 07 Oct 2020 18:34:47 |



US3602123

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:32

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-07T14:34:42', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'c18d5f27-e549-4207-9f64-4ff0e473c726' User entered 'No (N)' | System           | 07 Oct 2020 18:34:47 |
|  | System           | 07 Oct 2020 18:34:47 |

US3602123

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:32

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-07T14:34:43', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'c18d5f27-e549-4207-9f64-4ff0e473c726' | System           | 07 Oct 2020 18:34:47 |
| User entered 'None (1)'  | System           | 07 Oct 2020 18:34:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-07T14:34:45', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'c18d5f27-e549-4207-9f64-4ff0e473c726' User entered '07 Oct 2020 14:34' | System           | 07 Oct 2020 18:34:47 |
|   | System           | 07 Oct 2020 18:34:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '07 Oct 2020 12:00' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '08 Oct 2020 11:59' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 02 Oct 2020 19:46:47 |
| User entered 'Day 7' | System           | 02 Oct 2020 19:46:47 |

US3602123

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:32

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-08T19:51:25', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '43f7f35e-2b33-429a-94db-1e3c56aad5b8' User entered 'None (1)' | System           | 08 Oct 2020 23:51:39 |
|  | System           | 08 Oct 2020 23:51:39 |

US3602123

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:32

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-08T19:51:27', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '43f7f35e-2b33-429a-94db-1e3c56aad5b8' User entered 'No (N)' | System           | 08 Oct 2020 23:51:39 |
|  | System           | 08 Oct 2020 23:51:39 |



US3602123

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:32

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-08T19:51:34', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '43f7f35e-2b33-429a-94db-1e3c56aad5b8' User entered 'No (N)' | System           | 08 Oct 2020 23:51:39 |
|  | System           | 08 Oct 2020 23:51:39 |

US3602123

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:32

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-08T19:51:35', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '43f7f35e-2b33-429a-94db-1e3c56aad5b8' User entered 'None (1)' | System           | 08 Oct 2020 23:51:39 |
|  | System           | 08 Oct 2020 23:51:39 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-08T19:51:37', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '43f7f35e-2b33-429a-94db-1e3c56aad5b8' User entered '08 Oct 2020 19:51' | System           | 08 Oct 2020 23:51:39 |
|   | System           | 08 Oct 2020 23:51:39 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '08 Oct 2020 12:00' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '09 Oct 2020 11:59' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 02 Oct 2020 19:46:47 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:32**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-02T16:12:41', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'f4398423-db0b-4b91-8434-9a9550aa2912' User entered 'None (0)' | System           | 02 Oct 2020 20:13:07 |
|  | System           | 02 Oct 2020 20:13:07 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:32**

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-02T16:12:45', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'f4398423-db0b-4b91-8434-9a9550aa2912' User entered 'None (0)' | System           | 02 Oct 2020 20:13:07 |
|  | System           | 02 Oct 2020 20:13:07 |



**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:32**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-02T16:12:48', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'f4398423-db0b-4b91-8434-9a9550aa2912' User entered 'None (0)' | System           | 02 Oct 2020 20:13:07 |
|  | System           | 02 Oct 2020 20:13:07 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:32**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-02T16:12:51', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'f4398423-db0b-4b91-8434-9a9550aa2912' User entered 'None (0)' | System           | 02 Oct 2020 20:13:07 |
|  | System           | 02 Oct 2020 20:13:07 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:32**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-02T16:12:53', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'f4398423-db0b-4b91-8434-9a9550aa2912' User entered 'None (0)' | System           | 02 Oct 2020 20:13:07 |
|  | System           | 02 Oct 2020 20:13:07 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:32**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-02T16:12:56', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'f4398423-db0b-4b91-8434-9a9550aa2912' User entered 'None (0)' | System           | 02 Oct 2020 20:13:07 |
|  | System           | 02 Oct 2020 20:13:07 |

US3602123

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:32

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-02T16:13:01', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'f4398423-db0b-4b91-8434-9a9550aa2912' | System           | 02 Oct 2020 20:13:07 |
| User entered 'No (N)'  | System           | 02 Oct 2020 20:13:07 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-02T16:13:04', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'f4398423-db0b-4b91-8434-9a9550aa2912' User entered '02 Oct 2020 16:13' | System           | 02 Oct 2020 20:13:07 |
|   | System           | 02 Oct 2020 20:13:07 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '02 Oct 2020 15:52' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '02 Oct 2020 18:22' | System           | 02 Oct 2020 19:46:47 |



**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.                                | System           | 02 Oct 2020 19:46:47 |
| User entered 'Day 1, after vaccination (at home)' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:32**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-02T20:46:58', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'e72a0ba8-fd95-413e-b270-3000b2eee964' | System           | 03 Oct 2020 00:47:30 |
| User entered 'No interference with activity (1)'   | System           | 03 Oct 2020 00:47:30 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:32**

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-02T20:47:03', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'e72a0ba8-fd95-413e-b270-3000b2eee964' | System           | 03 Oct 2020 00:47:30 |
| User entered 'No interference with activity (1)'   | System           | 03 Oct 2020 00:47:30 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:32**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-02T20:47:06', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'e72a0ba8-fd95-413e-b270-3000b2eee964' User entered 'None (0)' | System           | 03 Oct 2020 00:47:30 |
|  | System           | 03 Oct 2020 00:47:30 |

US3602123

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:32

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-02T20:47:09', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'e72a0ba8-fd95-413e-b270-3000b2eee964' User entered 'None (0)' | System           | 03 Oct 2020 00:47:30 |
|  | System           | 03 Oct 2020 00:47:30 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:32**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-02T20:47:15', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'e72a0ba8-fd95-413e-b270-3000b2eee964' | System           | 03 Oct 2020 00:47:30 |
| User entered 'No interference with activity or 1-2 episodes/24 hours (1)'  | System           | 03 Oct 2020 00:47:30 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:32**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-02T20:47:19', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'e72a0ba8-fd95-413e-b270-3000b2eee964' User entered 'None (0)' | System           | 03 Oct 2020 00:47:30 |
|  | System           | 03 Oct 2020 00:47:30 |

US3602123

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:32

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-02T20:47:24', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'e72a0ba8-fd95-413e-b270-3000b2eee964' User entered 'No (N)' | System           | 03 Oct 2020 00:47:30 |
|  | System           | 03 Oct 2020 00:47:30 |



**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-02T20:47:26', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'e72a0ba8-fd95-413e-b270-3000b2eee964' User entered '02 Oct 2020 20:47' | System           | 03 Oct 2020 00:47:30 |
|   | System           | 03 Oct 2020 00:47:30 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '02 Oct 2020 19:17' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '03 Oct 2020 11:59' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 02 Oct 2020 19:46:47 |
| User entered 'Day 2' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:32**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-03T19:16:24', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'c904e351-a771-46e9-8b06-0cdd1ea2ab95' User entered 'None (0)' | System           | 03 Oct 2020 23:16:44 |
|  | System           | 03 Oct 2020 23:16:44 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:32**

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-03T19:16:27', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'c904e351-a771-46e9-8b06-0cdd1ea2ab95' User entered 'None (0)' | System           | 03 Oct 2020 23:16:44 |
|  | System           | 03 Oct 2020 23:16:44 |

US3602123

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:32

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-03T19:16:31', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'c904e351-a771-46e9-8b06-0cdd1ea2ab95' User entered 'None (0)' | System           | 03 Oct 2020 23:16:44 |
|  | System           | 03 Oct 2020 23:16:44 |

US3602123

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:32

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-03T19:16:32', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'c904e351-a771-46e9-8b06-0cdd1ea2ab95' User entered 'None (0)' | System           | 03 Oct 2020 23:16:44 |
|  | System           | 03 Oct 2020 23:16:44 |



**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:32**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-03T19:16:34', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'c904e351-a771-46e9-8b06-0cdd1ea2ab95' User entered 'None (0)' | System           | 03 Oct 2020 23:16:44 |
|  | System           | 03 Oct 2020 23:16:44 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:32**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-03T19:16:38', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'c904e351-a771-46e9-8b06-0cdd1ea2ab95' User entered 'None (0)' | System           | 03 Oct 2020 23:16:44 |
|  | System           | 03 Oct 2020 23:16:44 |

US3602123

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:32

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-03T19:16:40', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'c904e351-a771-46e9-8b06-0cdd1ea2ab95' User entered 'No (N)' | System           | 03 Oct 2020 23:16:44 |
|  | System           | 03 Oct 2020 23:16:44 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-03T19:16:43', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'c904e351-a771-46e9-8b06-0cdd1ea2ab95' User entered '03 Oct 2020 19:16' | System           | 03 Oct 2020 23:16:44 |
|   | System           | 03 Oct 2020 23:16:44 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '03 Oct 2020 12:00' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '04 Oct 2020 11:59' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 02 Oct 2020 19:46:47 |
| User entered 'Day 3' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:32**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-04T12:32:31', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'd27875db-96d4-41db-8c35-c730992b6620' User entered 'None (0)' | System           | 04 Oct 2020 16:32:46 |
|  | System           | 04 Oct 2020 16:32:46 |



**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:32**

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-04T12:32:33', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'd27875db-96d4-41db-8c35-c730992b6620' User entered 'None (0)' | System           | 04 Oct 2020 16:32:46 |
|  | System           | 04 Oct 2020 16:32:46 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:32**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-04T12:32:35', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'd27875db-96d4-41db-8c35-c730992b6620' User entered 'None (0)' | System           | 04 Oct 2020 16:32:46 |
|  | System           | 04 Oct 2020 16:32:46 |

US3602123

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:32

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-04T12:32:37', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'd27875db-96d4-41db-8c35-c730992b6620' User entered 'None (0)' | System           | 04 Oct 2020 16:32:46 |
|  | System           | 04 Oct 2020 16:32:46 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:32**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-04T12:32:38', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'd27875db-96d4-41db-8c35-c730992b6620' User entered 'None (0)' | System           | 04 Oct 2020 16:32:46 |
|  | System           | 04 Oct 2020 16:32:46 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:32**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-04T12:32:40', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'd27875db-96d4-41db-8c35-c730992b6620' User entered 'None (0)' | System           | 04 Oct 2020 16:32:46 |
|  | System           | 04 Oct 2020 16:32:46 |

US3602123

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:32

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-04T12:32:42', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'd27875db-96d4-41db-8c35-c730992b6620' User entered 'No (N)' | System           | 04 Oct 2020 16:32:46 |
|  | System           | 04 Oct 2020 16:32:46 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-04T12:32:45', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'd27875db-96d4-41db-8c35-c730992b6620' User entered '04 Oct 2020 12:32' | System           | 04 Oct 2020 16:32:46 |
|   | System           | 04 Oct 2020 16:32:46 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '04 Oct 2020 12:00' | System           | 02 Oct 2020 19:46:47 |



**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '05 Oct 2020 11:59' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 02 Oct 2020 19:46:47 |
| User entered 'Day 4' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:32**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-05T18:24:18', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '9c18b9c5-de6d-4711-80db-bbde1e5e7df6' User entered 'None (0)' | System           | 05 Oct 2020 22:24:38 |
|  | System           | 05 Oct 2020 22:24:38 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:32**

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-05T18:24:20', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '9c18b9c5-de6d-4711-80db-bbde1e5e7df6' User entered 'None (0)' | System           | 05 Oct 2020 22:24:38 |
|  | System           | 05 Oct 2020 22:24:38 |

US3602123

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:32

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-05T18:24:22', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '9c18b9c5-de6d-4711-80db-bbde1e5e7df6' User entered 'None (0)' | System           | 05 Oct 2020 22:24:38 |
|  | System           | 05 Oct 2020 22:24:38 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:32**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-05T18:24:25', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '9c18b9c5-de6d-4711-80db-bbde1e5e7df6' User entered 'None (0)' | System           | 05 Oct 2020 22:24:38 |
|  | System           | 05 Oct 2020 22:24:38 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:32**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-05T18:24:27', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '9c18b9c5-de6d-4711-80db-bbde1e5e7df6' User entered 'None (0)' | System           | 05 Oct 2020 22:24:38 |
|  | System           | 05 Oct 2020 22:24:38 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:32**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-05T18:24:29', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '9c18b9c5-de6d-4711-80db-bbde1e5e7df6' User entered 'None (0)' | System           | 05 Oct 2020 22:24:38 |
|  | System           | 05 Oct 2020 22:24:38 |



US3602123

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:32

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-05T18:24:32', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '9c18b9c5-de6d-4711-80db-bbde1e5e7df6' User entered 'No (N)' | System           | 05 Oct 2020 22:24:38 |
|  | System           | 05 Oct 2020 22:24:38 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-05T18:24:35', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '9c18b9c5-de6d-4711-80db-bbde1e5e7df6' User entered '05 Oct 2020 18:24' | System           | 05 Oct 2020 22:24:38 |
|   | System           | 05 Oct 2020 22:24:38 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '05 Oct 2020 12:00' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '06 Oct 2020 11:59' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 02 Oct 2020 19:46:47 |
| User entered 'Day 5' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:32**

**HEADACHE**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-06T18:27:19', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '4f92700c-7b6b-4acc-9b52-8b4bc5815193' User entered 'Any use of prescription pain reliever or System prevents daily activity (3)' | System           | 06 Oct 2020 22:27:41 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:32**

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-06T18:27:21', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '4f92700c-7b6b-4acc-9b52-8b4bc5815193' User entered 'None (0)' | System           | 06 Oct 2020 22:27:41 |
|  | System           | 06 Oct 2020 22:27:41 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:32**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-06T18:27:24', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '4f92700c-7b6b-4acc-9b52-8b4bc5815193' User entered 'None (0)' | System           | 06 Oct 2020 22:27:41 |
|  | System           | 06 Oct 2020 22:27:41 |



US3602123

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:32

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-06T18:27:26', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '4f92700c-7b6b-4acc-9b52-8b4bc5815193' User entered 'None (0)' | System           | 06 Oct 2020 22:27:41 |
|  | System           | 06 Oct 2020 22:27:41 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:32**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-06T18:27:31', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '4f92700c-7b6b-4acc-9b52-8b4bc5815193' | System           | 06 Oct 2020 22:27:41 |
| User entered 'No interference with activity or 1-2 episodes/24 hours (1)'  | System           | 06 Oct 2020 22:27:41 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:32**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-06T18:27:33', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '4f92700c-7b6b-4acc-9b52-8b4bc5815193' User entered 'None (0)' | System           | 06 Oct 2020 22:27:41 |
|  | System           | 06 Oct 2020 22:27:41 |

US3602123

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:32

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-06T18:27:36', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '4f92700c-7b6b-4acc-9b52-8b4bc5815193' User entered 'No (N)' | System           | 06 Oct 2020 22:27:41 |
|  | System           | 06 Oct 2020 22:27:41 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-06T18:27:38', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '4f92700c-7b6b-4acc-9b52-8b4bc5815193' User entered '06 Oct 2020 18:27' | System           | 06 Oct 2020 22:27:41 |
|   | System           | 06 Oct 2020 22:27:41 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '06 Oct 2020 12:00' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '07 Oct 2020 11:59' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 02 Oct 2020 19:46:47 |
| User entered 'Day 6' | System           | 02 Oct 2020 19:46:47 |



**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:32**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-07T14:34:50', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'dbe00a40-8558-40bb-95bc-5cc1d2e60d13' | System           | 07 Oct 2020 18:35:05 |
| User entered 'No interference with activity (1)'   | System           | 07 Oct 2020 18:35:05 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:32**

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-07T14:34:52', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'dbe00a40-8558-40bb-95bc-5cc1d2e60d13' User entered 'None (0)' | System           | 07 Oct 2020 18:35:05 |
|  | System           | 07 Oct 2020 18:35:05 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:32**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-07T14:34:53', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'dbe00a40-8558-40bb-95bc-5cc1d2e60d13' User entered 'None (0)' | System           | 07 Oct 2020 18:35:05 |
|  | System           | 07 Oct 2020 18:35:05 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:32**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-07T14:34:55', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'dbe00a40-8558-40bb-95bc-5cc1d2e60d13' User entered 'None (0)' | System           | 07 Oct 2020 18:35:05 |
|  | System           | 07 Oct 2020 18:35:05 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:32**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-07T14:34:57', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'dbe00a40-8558-40bb-95bc-5cc1d2e60d13' User entered 'None (0)' | System           | 07 Oct 2020 18:35:05 |
|  | System           | 07 Oct 2020 18:35:05 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:32**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-07T14:34:58', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'dbe00a40-8558-40bb-95bc-5cc1d2e60d13' User entered 'None (0)' | System           | 07 Oct 2020 18:35:05 |
|  | System           | 07 Oct 2020 18:35:05 |

US3602123

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:32

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-07T14:35:01', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'dbe00a40-8558-40bb-95bc-5cc1d2e60d13' User entered 'No (N)' | System           | 07 Oct 2020 18:35:05 |
|  | System           | 07 Oct 2020 18:35:05 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-07T14:35:03', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'dbe00a40-8558-40bb-95bc-5cc1d2e60d13' User entered '07 Oct 2020 14:35' | System           | 07 Oct 2020 18:35:05 |
|   | System           | 07 Oct 2020 18:35:05 |



**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '07 Oct 2020 12:00' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '08 Oct 2020 11:59' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 02 Oct 2020 19:46:47 |
| User entered 'Day 7' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:32**

**HEADACHE**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-08T19:51:49', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'c814d064-2175-4ef8-a642-54f39192f37f' User entered 'No interference with activity (1)' | System           | 08 Oct 2020 23:52:08 |
|   | System           | 08 Oct 2020 23:52:08 |

US3602123

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:13:32

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-08T19:51:50', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'c814d064-2175-4ef8-a642-54f39192f37f' User entered 'None (0)' | System           | 08 Oct 2020 23:52:08 |
|  | System           | 08 Oct 2020 23:52:08 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:32**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-08T19:51:52', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'c814d064-2175-4ef8-a642-54f39192f37f' User entered 'None (0)' | System           | 08 Oct 2020 23:52:08 |
|  | System           | 08 Oct 2020 23:52:08 |

US3602123

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:13:32

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-08T19:51:54', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'c814d064-2175-4ef8-a642-54f39192f37f' User entered 'None (0)' | System           | 08 Oct 2020 23:52:08 |
|  | System           | 08 Oct 2020 23:52:08 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:32**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-08T19:51:55', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'c814d064-2175-4ef8-a642-54f39192f37f' User entered 'None (0)' | System           | 08 Oct 2020 23:52:08 |
|  | System           | 08 Oct 2020 23:52:08 |



**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:32**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-08T19:51:57', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'c814d064-2175-4ef8-a642-54f39192f37f' User entered 'None (0)' | System           | 08 Oct 2020 23:52:08 |
|  | System           | 08 Oct 2020 23:52:08 |

US3602123

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:13:32

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-08T19:51:59', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'c814d064-2175-4ef8-a642-54f39192f37f' User entered 'No (N)' | System           | 08 Oct 2020 23:52:08 |
|  | System           | 08 Oct 2020 23:52:08 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-08T19:52:03', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'c814d064-2175-4ef8-a642-54f39192f37f' User entered '08 Oct 2020 19:52' | System           | 08 Oct 2020 23:52:08 |
|   | System           | 08 Oct 2020 23:52:08 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '08 Oct 2020 12:00' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '09 Oct 2020 11:59' | System           | 02 Oct 2020 19:46:47 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 07 Oct 2020 18:35:05 |
| User entered 'Day 8' | System           | 07 Oct 2020 18:35:05 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 10 Jun 2021 09:13:32**

Select one response below to indicate the intensity of your **HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-09T20:53:41', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '479b2ff8-853b-4dec-9053-6b6e670e45b9' | System           | 10 Oct 2020 00:53:46 |
| User entered 'No interference with activity (1)'   | System           | 10 Oct 2020 00:53:46 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-09T20:53:43', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '479b2ff8-853b-4dec-9053-6b6e670e45b9' User entered '09 Oct 2020 20:53' | System           | 10 Oct 2020 00:53:46 |
|   | System           | 10 Oct 2020 00:53:46 |



**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '09 Oct 2020 12:00' | System           | 07 Oct 2020 18:35:05 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '10 Oct 2020 11:59' | System           | 07 Oct 2020 18:35:05 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(9)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 08 Oct 2020 23:52:08 |
| User entered 'Day 9' | System           | 08 Oct 2020 23:52:08 |

US3602123

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 10 Jun 2021 09:13:32

Select one response below to indicate the intensity of your **HEADACHE**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
|                   |                  |                      |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(9)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time Stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
|                   |                  |                      |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(9)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '10 Oct 2020 12:00' | System           | 08 Oct 2020 23:52:08 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(9)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '11 Oct 2020 11:59' | System           | 08 Oct 2020 23:52:08 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(10)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.    | System           | 10 Oct 2020 00:53:46 |
| User entered 'Day 10' | System           | 10 Oct 2020 00:53:46 |



**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(10)**

**Generated On: 10 Jun 2021 09:13:32**

Select one response below to indicate the intensity of your **HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-11T13:42:26', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'ad999930-24e7-4f2b-8273-ecd20e1de5aa' User entered 'None (0)' | System           | 11 Oct 2020 17:42:34 |
|  | System           | 11 Oct 2020 17:42:34 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(10)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-11T13:42:31', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'ad999930-24e7-4f2b-8273-ecd20e1de5aa' | System           | 11 Oct 2020 17:42:34 |
| User entered '11 Oct 2020 13:42'   | System           | 11 Oct 2020 17:42:34 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(10)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '11 Oct 2020 12:00' | System           | 10 Oct 2020 00:53:46 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(10)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '12 Oct 2020 11:59' | System           | 10 Oct 2020 00:53:46 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 07 Oct 2020 18:35:05 |
| User entered 'Day 8' | System           | 07 Oct 2020 18:35:05 |

US3602123

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:13:32

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-09T20:53:49', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'baf22bbd-662f-4d94-a749-3783f7413208' User entered 'No (N)' | System           | 10 Oct 2020 00:53:56 |
|  | System           | 10 Oct 2020 00:53:56 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-09T20:53:55', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'baf22bbd-662f-4d94-a749-3783f7413208' User entered '09 Oct 2020 20:53' | System           | 10 Oct 2020 00:53:56 |
|   | System           | 10 Oct 2020 00:53:56 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '09 Oct 2020 12:00' | System           | 07 Oct 2020 18:35:05 |



**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '10 Oct 2020 11:59' | System           | 07 Oct 2020 18:35:05 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 08 Oct 2020 23:51:23 |
| User entered 'Day 9' | System           | 08 Oct 2020 23:51:23 |

US3602123

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 09:13:32

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
|                   |                  |                      |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
|                   |                  |                      |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '10 Oct 2020 12:00' | System           | 08 Oct 2020 23:51:23 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '11 Oct 2020 11:59' | System           | 08 Oct 2020 23:51:23 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.    | System           | 10 Oct 2020 00:53:38 |
| User entered 'Day 10' | System           | 10 Oct 2020 00:53:38 |

US3602123

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 09:13:32

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-11T13:42:36', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '36011485-5a3e-48dd-91b9-1f3567bd77cc' User entered 'No (N)' | System           | 11 Oct 2020 17:42:39 |
|  | System           | 11 Oct 2020 17:42:39 |



**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-11T13:42:38', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '36011485-5a3e-48dd-91b9-1f3567bd77cc' User entered '11 Oct 2020 13:42' | System           | 11 Oct 2020 17:42:39 |
|   | System           | 11 Oct 2020 17:42:39 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '11 Oct 2020 12:00' | System           | 10 Oct 2020 00:53:38 |

**US3602123**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '12 Oct 2020 11:59' | System           | 10 Oct 2020 00:53:38 |

**US3602123**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

[Was Contact Attempted?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 15:08:30 |

**US3602123**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '9 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 15:08:30 |

**US3602123**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.                  | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 15:08:30 |

**US3602123**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 15:08:30 |

**US3602123**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:32**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 15:01:02 |



**US3602123**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:32**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered 'I'  | System           | 27 Oct 2020 15:01:02 |

**US3602123**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

[Was Contact Attempted?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 15:09:54 |

US3602123

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:13:32

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)     | 14 Apr 2021 12:26:08 |
| User signature succeeded.  | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
| User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).             | (b) (4)<br>System    | 27 Oct 2020 15:12:01 |
| Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System). | System               | 27 Oct 2020 15:12:01 |
| User entered '16 Oct 2020' reason for change: Data Entry Error   | (b) (4), (b) (6)     | 27 Oct 2020 15:12:01 |
| User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).             | System               | 27 Oct 2020 15:09:54 |
| User entered '12 Oct 2020'   | (b) (4), (b) (6)     | 27 Oct 2020 15:09:54 |

**US3602123**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.                  | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 15:09:54 |

**US3602123**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 15:09:54 |

**US3602123**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:32**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 15:01:15 |

**US3602123**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:32**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered 'I'  | System           | 27 Oct 2020 15:01:15 |

**US3602123**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

[Was Contact Attempted?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 15:13:07 |



**US3602123**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '23 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 15:13:07 |

**US3602123**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.                  | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 15:13:07 |

**US3602123**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 15:13:07 |

**US3602123**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:32**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 15:01:38 |

**US3602123**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:32**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered 'I'  | System           | 27 Oct 2020 15:01:38 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:32**

[Was this visit performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 18:02:11 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:32**

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '27 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 18:02:11 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:32**

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.      | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 18:02:11 |



**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:32**

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered 'VISIT2' | System           | 27 Oct 2020 18:02:11 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Timepoint](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.                                | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User accepted default value 'Pre-Dose (PREDOSE)' | (b) (4), (b) (6) | 27 Oct 2020 18:05:44 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Were vital signs assessed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 18:05:44 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

**Date of assessment** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '27 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 18:05:44 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

**Time of assessment (00:00-23:59)**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '08:36'      | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 18:05:44 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered '27 Oct 2020 08:36' | System           | 27 Oct 2020 18:05:44 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Temperature \(xxx.x\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '97.8' F     | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 18:05:44 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Route of measurement](#)

| Audit                        | User                        | Time (GMT)           |
|------------------------------|-----------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.    | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Other (Other)' | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 18:05:44 |



**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[If Other, specify](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.                         | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Temporal/Forehead scanner was used' | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 18:05:44 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Pulse \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '76'         | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 18:05:44 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered 'bpm' | System           | 27 Oct 2020 18:05:44 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '18'         | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 18:05:44 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered 'breaths/min' | System           | 27 Oct 2020 18:05:44 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '123'        | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 18:05:44 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered 'mmHg' | System           | 27 Oct 2020 18:05:44 |

US3602123

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:13:32

Diastolic Blood Pressure (xxx)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '78'         | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 18:05:44 |



**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered 'mmHg' | System           | 27 Oct 2020 18:05:44 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Timepoint](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User accepted default value 'Post-Dose (POSTDOSE)' | (b) (4), (b) (6) | 27 Oct 2020 18:05:44 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Were vital signs assessed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 18:05:44 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

**Date of assessment** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '27 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 18:05:44 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

**Time of assessment (00:00-23:59)**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '10:44'      | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 18:05:44 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered '27 Oct 2020 10:44' | System           | 27 Oct 2020 18:05:44 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Temperature \(xxx.x\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '97.6' F     | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 18:05:44 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Route of measurement](#)

| Audit                        | User                        | Time (GMT)           |
|------------------------------|-----------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.    | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Other (Other)' | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 18:05:44 |



**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[If Other, specify](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.                         | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Temporal/Forehead scanner was used' | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 18:05:44 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Pulse \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '75'         | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 18:05:44 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered 'bpm' | System           | 27 Oct 2020 18:05:44 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '18'         | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 18:05:44 |

US3602123

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:13:32

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered 'breaths/min' | System           | 27 Oct 2020 18:05:44 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '135'        | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 18:05:44 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered 'mmHg' | System           | 27 Oct 2020 18:05:44 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '83'         | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 18:05:44 |



**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered 'mmHg' | System           | 27 Oct 2020 18:05:44 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:13:32**

[Was the physical examination performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 18:05:53 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:13:32**

**Date of examination (dd MMM yyyy)**

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '27 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 18:05:53 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:13:32**

[Was the pregnancy test performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 18:06:06 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:13:32**

**Date of test (dd MMM yyyy)**

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '27 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 18:06:06 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:13:32**

[Test performed](#)

| Audit                        | User                        | Time (GMT)           |
|------------------------------|-----------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.    | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Urine (URINE)' | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 18:06:06 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:13:32**

[Result](#)

| Audit                              | User                        | Time (GMT)           |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.          | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Negative (NEGATIVE)' | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 18:06:06 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:13:32**

[Was FSH sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 18:06:06 |



**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:13:32**

[Collection date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 18:06:06 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:13:32**

[Collection time](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 18:06:06 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:13:32**

[Collection date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered empty. | System           | 27 Oct 2020 18:06:06 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:32**

[Was study treatment given?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:32**

[If No, reason not given](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:32**

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:32**

[What was the study treatment?](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| Data hard locked.                   | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered 'MRNA-1273 OR PLACEBO' | System           | 27 Oct 2020 15:02:21 |

US3602123

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:13:32

What was the treatment date? (dd MMM yyyy)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '27 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 15:02:21 |



**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:32**

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '10:14'      | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:32**

[Treatment Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered '27 Oct 2020 10:14' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:32**

[Which arm was used to give treatment?](#)

| Audit                              | User                        | Time (GMT)           |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.          | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:32**

[What was the frequency of the study treatment dosing?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered 'ONCE' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:32**

[What was the route of administration for the study treatment?](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered 'INTRAMUSCULAR' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:32**

[Was the sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 18:06:33 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:32**

**Collection date** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '27 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 18:06:33 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:32**

[Collection time \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '08:36'      | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 18:06:33 |



**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:32**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered '27 Oct 2020 08:36' | System           | 27 Oct 2020 18:06:33 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 09:13:32**

**Collection date** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '27 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 18:06:47 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Lab Test](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | (b) (4), (b) (6) | 27 Oct 2020 18:06:47 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Was the sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 18:06:47 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Collection time \(00:00 - 23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '08:45'      | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 18:06:47 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered '27 Oct 2020 08:45' | System           | 27 Oct 2020 18:06:47 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Lab Test](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | (b) (4), (b) (6) | 27 Oct 2020 18:06:47 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Was the sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 18:06:47 |



**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Collection time \(00:00 - 23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 18:06:47 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Collection date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered empty. | System           | 27 Oct 2020 18:06:47 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:32**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 27 Oct 2020 18:06:53 |

**US3602123**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:32**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered 'I'  | System           | 27 Oct 2020 18:06:53 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 27 Oct 2020 15:02:21 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:32**

**Was TEMPERATURE taken?**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-27T11:03:19', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '45b92e84-6851-493d-93e6-d8a40cd5c237' User entered 'Yes (Y)' | System           | 27 Oct 2020 15:03:37 |
|   | System           | 27 Oct 2020 15:03:37 |

US3602123

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:13:32

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-27T11:03:24', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '45b92e84-6851-493d-93e6-d8a40cd5c237' User entered '97.6' | System           | 27 Oct 2020 15:03:37 |
|  | System           | 27 Oct 2020 15:03:37 |

US3602123

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:13:32

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-27T11:03:27', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '45b92e84-6851-493d-93e6-d8a40cd5c237' User entered 'No (N)' | System           | 27 Oct 2020 15:03:37 |
|  | System           | 27 Oct 2020 15:03:37 |



**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-27T11:03:30', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '45b92e84-6851-493d-93e6-d8a40cd5c237' User entered '27 Oct 2020 11:03' | System           | 27 Oct 2020 15:03:37 |
|   | System           | 27 Oct 2020 15:03:37 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '27 Oct 2020 10:34' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '27 Oct 2020 13:04' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.                                | System           | 27 Oct 2020 15:02:21 |
| User entered 'Day 1, after vaccination (at home)' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:32**

**Was TEMPERATURE taken?**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-28T05:58:14', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '5fa936c3-747a-4866-b5c8-f82f8cdb8748' User entered 'Yes (Y)' | System           | 28 Oct 2020 09:58:26 |
|   | System           | 28 Oct 2020 09:58:26 |

US3602123

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:13:32

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-28T05:58:18', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '5fa936c3-747a-4866-b5c8-f82f8cdb8748' User entered '98.0' | System           | 28 Oct 2020 09:58:26 |
|  | System           | 28 Oct 2020 09:58:26 |

US3602123

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:13:32

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-28T05:58:21', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '5fa936c3-747a-4866-b5c8-f82f8cdb8748' | System           | 28 Oct 2020 09:58:26 |
| User entered 'No (N)'  | System           | 28 Oct 2020 09:58:26 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-28T05:58:24', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '5fa936c3-747a-4866-b5c8-f82f8cdb8748' User entered '28 Oct 2020 05:58' | System           | 28 Oct 2020 09:58:26 |
|   | System           | 28 Oct 2020 09:58:26 |



**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '27 Oct 2020 13:59' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '28 Oct 2020 11:59' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 27 Oct 2020 15:02:21 |
| User entered 'Day 2' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:13:32**

**Was TEMPERATURE taken?**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-28T14:44:35', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '4f07b2c7-0543-4955-a179-d4def5e3f1fe' User entered 'Yes (Y)' | System           | 28 Oct 2020 18:45:38 |
|   | System           | 28 Oct 2020 18:45:38 |

US3602123

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:13:32

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-28T14:44:39', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '4f07b2c7-0543-4955-a179-d4def5e3f1fe' User entered '98.2' | System           | 28 Oct 2020 18:45:38 |
|  | System           | 28 Oct 2020 18:45:38 |

US3602123

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:13:32

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-28T14:44:42', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '4f07b2c7-0543-4955-a179-d4def5e3f1fe' User entered 'No (N)' | System           | 28 Oct 2020 18:45:38 |
|  | System           | 28 Oct 2020 18:45:38 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-28T14:44:44', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '4f07b2c7-0543-4955-a179-d4def5e3f1fe' User entered '28 Oct 2020 14:44' | System           | 28 Oct 2020 18:45:38 |
|   | System           | 28 Oct 2020 18:45:38 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '28 Oct 2020 12:00' | System           | 27 Oct 2020 15:02:21 |



**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '29 Oct 2020 11:59' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 27 Oct 2020 15:02:21 |
| User entered 'Day 3' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:13:32**

**Was TEMPERATURE taken?**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-29T20:02:45', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'f6dca2f4-b83a-4e14-bcbf-e4706dc85a04' User entered 'Yes (Y)' | System           | 30 Oct 2020 00:03:07 |
|   | System           | 30 Oct 2020 00:03:07 |

US3602123

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:13:32

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-29T20:02:48', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'f6dca2f4-b83a-4e14-bcbf-e4706dc85a04' User entered '98.0' | System           | 30 Oct 2020 00:03:07 |
|  | System           | 30 Oct 2020 00:03:07 |

US3602123

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:13:32

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-29T20:02:59', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'f6dca2f4-b83a-4e14-bcbf-e4706dc85a04' User entered 'No (N)' | System           | 30 Oct 2020 00:03:07 |
|  | System           | 30 Oct 2020 00:03:07 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-29T20:03:02', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'f6dca2f4-b83a-4e14-bcbf-e4706dc85a04' User entered '29 Oct 2020 20:03' | System           | 30 Oct 2020 00:03:07 |
|   | System           | 30 Oct 2020 00:03:07 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '29 Oct 2020 12:00' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '30 Oct 2020 11:59' | System           | 27 Oct 2020 15:02:21 |



**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 27 Oct 2020 15:02:21 |
| User entered 'Day 4' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:13:32**

**Was TEMPERATURE taken?**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-31T08:54:01', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '1c9f7523-6c53-4a5e-a57e-9dbd25ec1a3f' User entered 'Yes (Y)' | System           | 31 Oct 2020 12:54:13 |
|   | System           | 31 Oct 2020 12:54:13 |

US3602123

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:13:32

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-31T08:54:08', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '1c9f7523-6c53-4a5e-a57e-9dbd25ec1a3f' User entered '98.0' | System           | 31 Oct 2020 12:54:13 |
|  | System           | 31 Oct 2020 12:54:13 |

US3602123

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:13:32

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-31T08:54:09', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '1c9f7523-6c53-4a5e-a57e-9dbd25ec1a3f' User entered 'No (N)' | System           | 31 Oct 2020 12:54:13 |
|  | System           | 31 Oct 2020 12:54:13 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-31T08:54:12', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '1c9f7523-6c53-4a5e-a57e-9dbd25ec1a3f' User entered '31 Oct 2020 08:54' | System           | 31 Oct 2020 12:54:13 |
|   | System           | 31 Oct 2020 12:54:13 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '30 Oct 2020 12:00' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '31 Oct 2020 11:59' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 27 Oct 2020 15:02:21 |
| User entered 'Day 5' | System           | 27 Oct 2020 15:02:21 |



US3602123

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:13:32

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-01T06:09:56', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'b170bb3a-5d32-4ba5-ab89-29d04a815a71' User entered 'Yes (Y)' | System           | 01 Nov 2020 11:10:09 |
|   | System           | 01 Nov 2020 11:10:09 |

US3602123

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:13:32

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-01T06:10:01', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'b170bb3a-5d32-4ba5-ab89-29d04a815a71' User entered '98.1' | System           | 01 Nov 2020 11:10:09 |
|  | System           | 01 Nov 2020 11:10:09 |

US3602123

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:13:32

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-01T06:10:03', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'b170bb3a-5d32-4ba5-ab89-29d04a815a71' | System           | 01 Nov 2020 11:10:09 |
| User entered 'No (N)'  | System           | 01 Nov 2020 11:10:09 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-01T06:10:06', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'b170bb3a-5d32-4ba5-ab89-29d04a815a71' User entered '01 Nov 2020 06:10' | System           | 01 Nov 2020 11:10:09 |
|   | System           | 01 Nov 2020 11:10:09 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '31 Oct 2020 12:00' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '01 Nov 2020 11:59' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 27 Oct 2020 15:02:21 |
| User entered 'Day 6' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:13:32**

**Was TEMPERATURE taken?**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-01T15:59:49', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '2cae4bd4-f495-4ab1-8c20-6c22036ba644' User entered 'Yes (Y)' | System           | 01 Nov 2020 21:00:00 |
|   | System           | 01 Nov 2020 21:00:00 |



US3602123

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:13:32

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-01T15:59:53', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '2cae4bd4-f495-4ab1-8c20-6c22036ba644' User entered '97.9' | System           | 01 Nov 2020 21:00:00 |
|  | System           | 01 Nov 2020 21:00:00 |

US3602123

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:13:32

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-01T15:59:56', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '2cae4bd4-f495-4ab1-8c20-6c22036ba644' | System           | 01 Nov 2020 21:00:00 |
| User entered 'No (N)'  | System           | 01 Nov 2020 21:00:00 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-01T15:59:58', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '2cae4bd4-f495-4ab1-8c20-6c22036ba644' User entered '01 Nov 2020 15:59' | System           | 01 Nov 2020 21:00:00 |
|   | System           | 01 Nov 2020 21:00:00 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '01 Nov 2020 12:00' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '02 Nov 2020 11:59' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 27 Oct 2020 15:02:21 |
| User entered 'Day 7' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:13:32**

**Was TEMPERATURE taken?**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-02T18:12:51', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '06014234-30da-4cf0-b799-a764e9c93115' User entered 'Yes (Y)' | System           | 02 Nov 2020 23:13:06 |
|   | System           | 02 Nov 2020 23:13:06 |

US3602123

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:13:32

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-02T18:12:56', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '06014234-30da-4cf0-b799-a764e9c93115' User entered '97.6' | System           | 02 Nov 2020 23:13:06 |
|  | System           | 02 Nov 2020 23:13:06 |



US3602123

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:13:32

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-02T18:12:59', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '06014234-30da-4cf0-b799-a764e9c93115' User entered 'No (N)' | System           | 02 Nov 2020 23:13:06 |
|  | System           | 02 Nov 2020 23:13:06 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-02T18:13:01', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '06014234-30da-4cf0-b799-a764e9c93115' User entered '02 Nov 2020 18:13' | System           | 02 Nov 2020 23:13:06 |
|   | System           | 02 Nov 2020 23:13:06 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '02 Nov 2020 12:00' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '03 Nov 2020 11:59' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 27 Oct 2020 15:02:21 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 27 Oct 2020 15:02:21 |

US3602123

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:32

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-27T11:03:35', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '38300e94-5e64-467d-bed3-b4154895ca93' User entered 'None (1)' | System           | 27 Oct 2020 15:03:48 |
|  | System           | 27 Oct 2020 15:03:48 |

US3602123

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:32

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-27T11:03:38', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '38300e94-5e64-467d-bed3-b4154895ca93' User entered 'No (N)' | System           | 27 Oct 2020 15:03:48 |
|  | System           | 27 Oct 2020 15:03:48 |

US3602123

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:32

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-27T11:03:40', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '38300e94-5e64-467d-bed3-b4154895ca93' User entered 'No (N)' | System           | 27 Oct 2020 15:03:48 |
|  | System           | 27 Oct 2020 15:03:48 |



US3602123

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:13:32

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-27T11:03:41', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '38300e94-5e64-467d-bed3-b4154895ca93' User entered 'None (1)' | System           | 27 Oct 2020 15:03:48 |
|  | System           | 27 Oct 2020 15:03:48 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-27T11:03:45', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '38300e94-5e64-467d-bed3-b4154895ca93' User entered '27 Oct 2020 11:03' | System           | 27 Oct 2020 15:03:48 |
|   | System           | 27 Oct 2020 15:03:48 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '27 Oct 2020 10:34' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '27 Oct 2020 13:04' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.                                | System           | 27 Oct 2020 15:02:21 |
| User entered 'Day 1, after vaccination (at home)' | System           | 27 Oct 2020 15:02:21 |

US3602123

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:32

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-28T05:58:27', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '65edc926-a341-49c4-bcc4-eb8981d27807' User entered 'None (1)' | System           | 28 Oct 2020 09:58:56 |
|  | System           | 28 Oct 2020 09:58:56 |

US3602123

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:32

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-28T05:58:32', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '65edc926-a341-49c4-bcc4-eb8981d27807' User entered 'No (N)' | System           | 28 Oct 2020 09:58:56 |
|  | System           | 28 Oct 2020 09:58:56 |

US3602123

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:32

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-28T05:58:35', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '65edc926-a341-49c4-bcc4-eb8981d27807' User entered 'No (N)' | System           | 28 Oct 2020 09:58:56 |
|  | System           | 28 Oct 2020 09:58:56 |



US3602123

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:13:32

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-28T05:58:50', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '65edc926-a341-49c4-bcc4-eb8981d27807' User entered 'None (1)' | System           | 28 Oct 2020 09:58:56 |
|  | System           | 28 Oct 2020 09:58:56 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-28T05:58:53', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '65edc926-a341-49c4-bcc4-eb8981d27807' User entered '28 Oct 2020 05:58' | System           | 28 Oct 2020 09:58:56 |
|   | System           | 28 Oct 2020 09:58:56 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '27 Oct 2020 13:59' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '28 Oct 2020 11:59' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 27 Oct 2020 15:02:21 |
| User entered 'Day 2' | System           | 27 Oct 2020 15:02:21 |

US3602123

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:32

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-28T14:44:48', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '40486324-9779-422b-8bed-673c14d4599a' | System           | 28 Oct 2020 18:45:45 |
| User entered 'None (1)'  | System           | 28 Oct 2020 18:45:45 |

US3602123

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:32

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-28T14:44:50', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '40486324-9779-422b-8bed-673c14d4599a' | System           | 28 Oct 2020 18:45:45 |
| User entered 'No (N)'  | System           | 28 Oct 2020 18:45:45 |

US3602123

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:32

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-28T14:44:52', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '40486324-9779-422b-8bed-673c14d4599a' User entered 'No (N)' | System           | 28 Oct 2020 18:45:45 |
|  | System           | 28 Oct 2020 18:45:45 |



US3602123

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:13:32

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-28T14:44:54', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '40486324-9779-422b-8bed-673c14d4599a' | System           | 28 Oct 2020 18:45:45 |
| User entered 'None (1)'  | System           | 28 Oct 2020 18:45:45 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-28T14:44:56', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '40486324-9779-422b-8bed-673c14d4599a' User entered '28 Oct 2020 14:44' | System           | 28 Oct 2020 18:45:45 |
|   | System           | 28 Oct 2020 18:45:45 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '28 Oct 2020 12:00' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '29 Oct 2020 11:59' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 27 Oct 2020 15:02:21 |
| User entered 'Day 3' | System           | 27 Oct 2020 15:02:21 |

US3602123

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:32

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-29T20:03:05', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '34ab7c8d-9f06-4749-b9f5-a3e93609712d' User entered 'None (1)' | System           | 30 Oct 2020 00:03:16 |
|  | System           | 30 Oct 2020 00:03:16 |

US3602123

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:32

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-29T20:03:06', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '34ab7c8d-9f06-4749-b9f5-a3e93609712d' User entered 'No (N)' | System           | 30 Oct 2020 00:03:16 |
|  | System           | 30 Oct 2020 00:03:16 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:13:32**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-29T20:03:08', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '34ab7c8d-9f06-4749-b9f5-a3e93609712d' User entered 'No (N)' | System           | 30 Oct 2020 00:03:16 |
|  | System           | 30 Oct 2020 00:03:16 |



US3602123

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:13:32

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-29T20:03:10', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '34ab7c8d-9f06-4749-b9f5-a3e93609712d' User entered 'None (1)' | System           | 30 Oct 2020 00:03:16 |
|  | System           | 30 Oct 2020 00:03:16 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-29T20:03:13', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '34ab7c8d-9f06-4749-b9f5-a3e93609712d' User entered '29 Oct 2020 20:03' | System           | 30 Oct 2020 00:03:16 |
|   | System           | 30 Oct 2020 00:03:16 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '29 Oct 2020 12:00' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '30 Oct 2020 11:59' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 27 Oct 2020 15:02:21 |
| User entered 'Day 4' | System           | 27 Oct 2020 15:02:21 |

US3602123

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:32

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-31T08:54:15', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '0b2928c6-6ce7-4988-b027-75ddb1439e23' | System           | 31 Oct 2020 12:54:23 |
| User entered 'None (1)'  | System           | 31 Oct 2020 12:54:23 |

US3602123

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:32

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-31T08:54:16', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '0b2928c6-6ce7-4988-b027-75ddb1439e23' User entered 'No (N)' | System           | 31 Oct 2020 12:54:23 |
|  | System           | 31 Oct 2020 12:54:23 |

US3602123

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:32

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-31T08:54:18', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '0b2928c6-6ce7-4988-b027-75ddb1439e23' User entered 'No (N)' | System           | 31 Oct 2020 12:54:23 |
|  | System           | 31 Oct 2020 12:54:23 |



US3602123

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:13:32

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-31T08:54:19', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '0b2928c6-6ce7-4988-b027-75ddb1439e23' | System           | 31 Oct 2020 12:54:23 |
| User entered 'None (1)'  | System           | 31 Oct 2020 12:54:23 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-31T08:54:21', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '0b2928c6-6ce7-4988-b027-75ddb1439e23' User entered '31 Oct 2020 08:54' | System           | 31 Oct 2020 12:54:23 |
|   | System           | 31 Oct 2020 12:54:23 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '30 Oct 2020 12:00' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '31 Oct 2020 11:59' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 27 Oct 2020 15:02:21 |
| User entered 'Day 5' | System           | 27 Oct 2020 15:02:21 |

US3602123

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:32

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-01T06:10:09', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'c80e20d6-4e02-4904-98a9-74d6714dd349' | System           | 01 Nov 2020 11:10:20 |
| User entered 'None (1)'  | System           | 01 Nov 2020 11:10:20 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:13:32**

Is there any **REDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-01T06:10:12', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'c80e20d6-4e02-4904-98a9-74d6714dd349' User entered 'No (N)' | System           | 01 Nov 2020 11:10:20 |
|  | System           | 01 Nov 2020 11:10:20 |

US3602123

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:32

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-01T06:10:14', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'c80e20d6-4e02-4904-98a9-74d6714dd349' User entered 'No (N)' | System           | 01 Nov 2020 11:10:20 |
|  | System           | 01 Nov 2020 11:10:20 |



US3602123

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:13:32

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-01T06:10:15', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'c80e20d6-4e02-4904-98a9-74d6714dd349' User entered 'None (1)' | System           | 01 Nov 2020 11:10:20 |
|  | System           | 01 Nov 2020 11:10:20 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-01T06:10:18', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'c80e20d6-4e02-4904-98a9-74d6714dd349' User entered '01 Nov 2020 06:10' | System           | 01 Nov 2020 11:10:20 |
|   | System           | 01 Nov 2020 11:10:20 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '31 Oct 2020 12:00' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '01 Nov 2020 11:59' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 27 Oct 2020 15:02:21 |
| User entered 'Day 6' | System           | 27 Oct 2020 15:02:21 |

US3602123

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:32

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-01T16:00:02', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'd0d32650-ea89-4dd9-b070-200e67e10767' | System           | 01 Nov 2020 21:00:13 |
| User entered 'None (1)'  | System           | 01 Nov 2020 21:00:13 |

US3602123

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:32

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-01T16:00:03', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'd0d32650-ea89-4dd9-b070-200e67e10767' User entered 'No (N)' | System           | 01 Nov 2020 21:00:13 |
|  | System           | 01 Nov 2020 21:00:13 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:13:32**

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-01T16:00:06', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'd0d32650-ea89-4dd9-b070-200e67e10767' User entered 'No (N)' | System           | 01 Nov 2020 21:00:13 |
|  | System           | 01 Nov 2020 21:00:13 |



US3602123

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:13:32

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-01T16:00:07', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'd0d32650-ea89-4dd9-b070-200e67e10767' User entered 'None (1)' | System           | 01 Nov 2020 21:00:13 |
|  | System           | 01 Nov 2020 21:00:13 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-01T16:00:10', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'd0d32650-ea89-4dd9-b070-200e67e10767' User entered '01 Nov 2020 16:00' | System           | 01 Nov 2020 21:00:13 |
|   | System           | 01 Nov 2020 21:00:13 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '01 Nov 2020 12:00' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '02 Nov 2020 11:59' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 27 Oct 2020 15:02:21 |
| User entered 'Day 7' | System           | 27 Oct 2020 15:02:21 |

US3602123

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:32

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-02T18:13:05', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'b155f83c-5541-4f05-86ad-db76583af29d' | System           | 02 Nov 2020 23:13:16 |
| User entered 'None (1)'  | System           | 02 Nov 2020 23:13:16 |

US3602123

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:32

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-02T18:13:08', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'b155f83c-5541-4f05-86ad-db76583af29d' User entered 'No (N)' | System           | 02 Nov 2020 23:13:16 |
|  | System           | 02 Nov 2020 23:13:16 |

US3602123

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:32

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-02T18:13:10', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'b155f83c-5541-4f05-86ad-db76583af29d' User entered 'No (N)' | System           | 02 Nov 2020 23:13:16 |
|  | System           | 02 Nov 2020 23:13:16 |



US3602123

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:13:32

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-02T18:13:11', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'b155f83c-5541-4f05-86ad-db76583af29d' User entered 'None (1)' | System           | 02 Nov 2020 23:13:16 |
|  | System           | 02 Nov 2020 23:13:16 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-02T18:13:14', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'b155f83c-5541-4f05-86ad-db76583af29d' User entered '02 Nov 2020 18:13' | System           | 02 Nov 2020 23:13:16 |
|   | System           | 02 Nov 2020 23:13:16 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '02 Nov 2020 12:00' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '03 Nov 2020 11:59' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 27 Oct 2020 15:02:21 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:32**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-27T11:03:49', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'd082c899-24b7-4479-8539-deec8284bd5b' User entered 'None (0)' | System           | 27 Oct 2020 15:04:08 |
|  | System           | 27 Oct 2020 15:04:08 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:32**

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-27T11:03:51', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'd082c899-24b7-4479-8539-deec8284bd5b' User entered 'None (0)' | System           | 27 Oct 2020 15:04:08 |
|  | System           | 27 Oct 2020 15:04:08 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:32**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-27T11:03:52', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'd082c899-24b7-4479-8539-deec8284bd5b' User entered 'None (0)' | System           | 27 Oct 2020 15:04:08 |
|  | System           | 27 Oct 2020 15:04:08 |



**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:32**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-27T11:03:54', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'd082c899-24b7-4479-8539-deec8284bd5b' User entered 'None (0)' | System           | 27 Oct 2020 15:04:08 |
|  | System           | 27 Oct 2020 15:04:08 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:32**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-27T11:03:55', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'd082c899-24b7-4479-8539-deec8284bd5b' User entered 'None (0)' | System           | 27 Oct 2020 15:04:08 |
|  | System           | 27 Oct 2020 15:04:08 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:32**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-27T11:03:57', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'd082c899-24b7-4479-8539-deec8284bd5b' User entered 'None (0)' | System           | 27 Oct 2020 15:04:08 |
|  | System           | 27 Oct 2020 15:04:08 |

US3602123

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:13:32

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-27T11:03:59', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'd082c899-24b7-4479-8539-deec8284bd5b' User entered 'No (N)' | System           | 27 Oct 2020 15:04:08 |
|  | System           | 27 Oct 2020 15:04:08 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-27T11:04:01', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'd082c899-24b7-4479-8539-deec8284bd5b' User entered '27 Oct 2020 11:04' | System           | 27 Oct 2020 15:04:08 |
|   | System           | 27 Oct 2020 15:04:08 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '27 Oct 2020 10:34' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '27 Oct 2020 13:04' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.                                | System           | 27 Oct 2020 15:02:21 |
| User entered 'Day 1, after vaccination (at home)' | System           | 27 Oct 2020 15:02:21 |



**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:32**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-28T05:58:56', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'ccf683bd-4c73-42cd-99c9-825db25e1eef' | System           | 28 Oct 2020 09:59:24 |
| User entered 'No interference with activity (1)'   | System           | 28 Oct 2020 09:59:24 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:32**

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-28T05:59:00', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'ccf683bd-4c73-42cd-99c9-825db25e1eef' | System           | 28 Oct 2020 09:59:24 |
| User entered 'No interference with activity (1)'   | System           | 28 Oct 2020 09:59:24 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:32**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-28T05:59:05', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'ccf683bd-4c73-42cd-99c9-825db25e1eef' User entered 'None (0)' | System           | 28 Oct 2020 09:59:24 |
|  | System           | 28 Oct 2020 09:59:24 |

US3602123

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:32

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-28T05:59:10', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'ccf683bd-4c73-42cd-99c9-825db25e1eef' User entered 'None (0)' | System           | 28 Oct 2020 09:59:24 |
|  | System           | 28 Oct 2020 09:59:24 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:32**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-28T05:59:13', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'ccf683bd-4c73-42cd-99c9-825db25e1eef' User entered 'None (0)' | System           | 28 Oct 2020 09:59:24 |
|  | System           | 28 Oct 2020 09:59:24 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:32**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-28T05:59:15', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'ccf683bd-4c73-42cd-99c9-825db25e1eef' User entered 'None (0)' | System           | 28 Oct 2020 09:59:24 |
|  | System           | 28 Oct 2020 09:59:24 |

US3602123

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:13:32

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-28T05:59:18', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'ccf683bd-4c73-42cd-99c9-825db25e1eef' User entered 'No (N)' | System           | 28 Oct 2020 09:59:24 |
|  | System           | 28 Oct 2020 09:59:24 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-28T05:59:20', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'ccf683bd-4c73-42cd-99c9-825db25e1eef' User entered '28 Oct 2020 05:59' | System           | 28 Oct 2020 09:59:24 |
|   | System           | 28 Oct 2020 09:59:24 |



**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '27 Oct 2020 13:59' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '28 Oct 2020 11:59' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 27 Oct 2020 15:02:21 |
| User entered 'Day 2' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:32**

**HEADACHE**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-28T14:45:01', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '70533743-7996-41de-82bb-ce84fbedc0c1' User entered 'No interference with activity (1)' | System           | 30 Oct 2020 00:02:48 |
|   |                  |                      |
|   | System           | 30 Oct 2020 00:02:48 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:32**

**FATIGUE**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-28T14:45:08', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '70533743-7996-41de-82bb-ce84fbedc0c1' User entered 'Some interference with activity (2)' | System           | 30 Oct 2020 00:02:48 |
|   |                  |                      |
|   | System           | 30 Oct 2020 00:02:48 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:32**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-28T14:45:11', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '70533743-7996-41de-82bb-ce84fbedc0c1' User entered 'None (0)' | System           | 30 Oct 2020 00:02:48 |
|  | System           | 30 Oct 2020 00:02:48 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:32**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-28T14:45:13', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '70533743-7996-41de-82bb-ce84fbedc0c1' User entered 'None (0)' | System           | 30 Oct 2020 00:02:48 |
|  | System           | 30 Oct 2020 00:02:48 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:32**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-28T14:45:16', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '70533743-7996-41de-82bb-ce84fbedc0c1' User entered 'None (0)' | System           | 30 Oct 2020 00:02:48 |
|  | System           | 30 Oct 2020 00:02:48 |



**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:32**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-28T14:45:19', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '70533743-7996-41de-82bb-ce84fbedc0c1' User entered 'None (0)' | System           | 30 Oct 2020 00:02:48 |
|  | System           | 30 Oct 2020 00:02:48 |

US3602123

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:13:32

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-28T14:45:22', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '70533743-7996-41de-82bb-ce84fbedc0c1' User entered 'No (N)' | System           | 30 Oct 2020 00:02:48 |
|  | System           | 30 Oct 2020 00:02:48 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-28T14:45:24', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '70533743-7996-41de-82bb-ce84fbedc0c1' User entered '28 Oct 2020 14:45' | System           | 30 Oct 2020 00:02:48 |
|   | System           | 30 Oct 2020 00:02:48 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '28 Oct 2020 12:00' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '29 Oct 2020 11:59' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 27 Oct 2020 15:02:21 |
| User entered 'Day 3' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:32**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-29T20:03:17', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '165cee8a-3867-4f3e-8c2b-e48aa2e3726a' User entered 'None (0)' | System           | 30 Oct 2020 00:03:30 |
|  | System           | 30 Oct 2020 00:03:30 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:32**

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-29T20:03:19', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '165cee8a-3867-4f3e-8c2b-e48aa2e3726a' User entered 'None (0)' | System           | 30 Oct 2020 00:03:30 |
|  | System           | 30 Oct 2020 00:03:30 |



**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:32**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-29T20:03:20', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '165cee8a-3867-4f3e-8c2b-e48aa2e3726a' User entered 'None (0)' | System           | 30 Oct 2020 00:03:30 |
|  | System           | 30 Oct 2020 00:03:30 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:32**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-29T20:03:21', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '165cee8a-3867-4f3e-8c2b-e48aa2e3726a' User entered 'None (0)' | System           | 30 Oct 2020 00:03:30 |
|  | System           | 30 Oct 2020 00:03:30 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:32**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-29T20:03:23', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '165cee8a-3867-4f3e-8c2b-e48aa2e3726a' User entered 'None (0)' | System           | 30 Oct 2020 00:03:30 |
|  | System           | 30 Oct 2020 00:03:30 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:32**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-29T20:03:24', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '165cee8a-3867-4f3e-8c2b-e48aa2e3726a' User entered 'None (0)' | System           | 30 Oct 2020 00:03:30 |
|  | System           | 30 Oct 2020 00:03:30 |

US3602123

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:13:32

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-29T20:03:26', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '165cee8a-3867-4f3e-8c2b-e48aa2e3726a' User entered 'No (N)' | System           | 30 Oct 2020 00:03:30 |
|  | System           | 30 Oct 2020 00:03:30 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-29T20:03:28', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '165cee8a-3867-4f3e-8c2b-e48aa2e3726a' User entered '29 Oct 2020 20:03' | System           | 30 Oct 2020 00:03:30 |
|   | System           | 30 Oct 2020 00:03:30 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '29 Oct 2020 12:00' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '30 Oct 2020 11:59' | System           | 27 Oct 2020 15:02:21 |



**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 27 Oct 2020 15:02:21 |
| User entered 'Day 4' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:32**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-31T08:54:24', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'a6ff97e7-d89c-4422-a1b1-6057922d2aab' User entered 'None (0)' | System           | 31 Oct 2020 12:54:39 |
|  | System           | 31 Oct 2020 12:54:39 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:32**

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-31T08:54:25', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'a6ff97e7-d89c-4422-a1b1-6057922d2aab' User entered 'None (0)' | System           | 31 Oct 2020 12:54:39 |
|  | System           | 31 Oct 2020 12:54:39 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:32**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-31T08:54:26', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'a6ff97e7-d89c-4422-a1b1-6057922d2aab' User entered 'None (0)' | System           | 31 Oct 2020 12:54:39 |
|  | System           | 31 Oct 2020 12:54:39 |

US3602123

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:32

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-31T08:54:28', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'a6ff97e7-d89c-4422-a1b1-6057922d2aab' User entered 'None (0)' | System           | 31 Oct 2020 12:54:39 |
|  | System           | 31 Oct 2020 12:54:39 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:32**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-31T08:54:29', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'a6ff97e7-d89c-4422-a1b1-6057922d2aab' User entered 'None (0)' | System           | 31 Oct 2020 12:54:39 |
|  | System           | 31 Oct 2020 12:54:39 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:32**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-31T08:54:30', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'a6ff97e7-d89c-4422-a1b1-6057922d2aab' User entered 'None (0)' | System           | 31 Oct 2020 12:54:39 |
|  | System           | 31 Oct 2020 12:54:39 |

US3602123

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:13:32

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-31T08:54:32', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'a6ff97e7-d89c-4422-a1b1-6057922d2aab' User entered 'No (N)' | System           | 31 Oct 2020 12:54:39 |
|  | System           | 31 Oct 2020 12:54:39 |



**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-10-31T08:54:34', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'a6ff97e7-d89c-4422-a1b1-6057922d2aab' User entered '31 Oct 2020 08:54' | System           | 31 Oct 2020 12:54:39 |
|   | System           | 31 Oct 2020 12:54:39 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '30 Oct 2020 12:00' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '31 Oct 2020 11:59' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 27 Oct 2020 15:02:21 |
| User entered 'Day 5' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:32**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-01T06:10:21', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '90d9a82b-a46d-4fd3-98b4-fcd849fa64cb' User entered 'None (0)' | System           | 01 Nov 2020 11:10:38 |
|  | System           | 01 Nov 2020 11:10:38 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:32**

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-01T06:10:23', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '90d9a82b-a46d-4fd3-98b4-fcd849fa64cb' User entered 'None (0)' | System           | 01 Nov 2020 11:10:38 |
|  | System           | 01 Nov 2020 11:10:38 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:32**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-01T06:10:24', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '90d9a82b-a46d-4fd3-98b4-fcd849fa64cb' User entered 'None (0)' | System           | 01 Nov 2020 11:10:38 |
|  | System           | 01 Nov 2020 11:10:38 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:32**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-01T06:10:25', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '90d9a82b-a46d-4fd3-98b4-fcd849fa64cb' User entered 'None (0)' | System           | 01 Nov 2020 11:10:38 |
|  | System           | 01 Nov 2020 11:10:38 |



**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:32**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-01T06:10:26', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '90d9a82b-a46d-4fd3-98b4-fcd849fa64cb' User entered 'None (0)' | System           | 01 Nov 2020 11:10:38 |
|  | System           | 01 Nov 2020 11:10:38 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:32**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-01T06:10:32', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '90d9a82b-a46d-4fd3-98b4-fcd849fa64cb' User entered 'None (0)' | System           | 01 Nov 2020 11:10:38 |
|  | System           | 01 Nov 2020 11:10:38 |

US3602123

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:13:32

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-01T06:10:34', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '90d9a82b-a46d-4fd3-98b4-fcd849fa64cb' User entered 'No (N)' | System           | 01 Nov 2020 11:10:38 |
|  | System           | 01 Nov 2020 11:10:38 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-01T06:10:36', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '90d9a82b-a46d-4fd3-98b4-fcd849fa64cb' User entered '01 Nov 2020 06:10' | System           | 01 Nov 2020 11:10:38 |
|   | System           | 01 Nov 2020 11:10:38 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '31 Oct 2020 12:00' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '01 Nov 2020 11:59' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 27 Oct 2020 15:02:21 |
| User entered 'Day 6' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:32**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-01T16:00:13', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '992adec6-1db3-4cda-a225-7f6d64593793' User entered 'None (0)' | System           | 01 Nov 2020 21:00:29 |
|  | System           | 01 Nov 2020 21:00:29 |



**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:32**

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-01T16:00:14', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '992adec6-1db3-4cda-a225-7f6d64593793' User entered 'None (0)' | System           | 01 Nov 2020 21:00:29 |
|  | System           | 01 Nov 2020 21:00:29 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:32**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-01T16:00:16', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '992adec6-1db3-4cda-a225-7f6d64593793' User entered 'None (0)' | System           | 01 Nov 2020 21:00:29 |
|  | System           | 01 Nov 2020 21:00:29 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:32**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-01T16:00:17', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '992adec6-1db3-4cda-a225-7f6d64593793' User entered 'None (0)' | System           | 01 Nov 2020 21:00:29 |
|  | System           | 01 Nov 2020 21:00:29 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:32**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-01T16:00:19', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '992adec6-1db3-4cda-a225-7f6d64593793' User entered 'None (0)' | System           | 01 Nov 2020 21:00:29 |
|  | System           | 01 Nov 2020 21:00:29 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:32**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-01T16:00:21', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '992adec6-1db3-4cda-a225-7f6d64593793' User entered 'None (0)' | System           | 01 Nov 2020 21:00:29 |
|  | System           | 01 Nov 2020 21:00:29 |

US3602123

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:13:32

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-01T16:00:23', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '992adec6-1db3-4cda-a225-7f6d64593793' User entered 'Yes (Y)' | System           | 01 Nov 2020 21:00:29 |
|   | System           | 01 Nov 2020 21:00:29 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-01T16:00:25', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '992adec6-1db3-4cda-a225-7f6d64593793' User entered '01 Nov 2020 16:00' | System           | 01 Nov 2020 21:00:29 |
|   | System           | 01 Nov 2020 21:00:29 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '01 Nov 2020 12:00' | System           | 27 Oct 2020 15:02:21 |



**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '02 Nov 2020 11:59' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| Data entry locked.   | System           | 27 Oct 2020 15:02:21 |
| User entered 'Day 7' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:32**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-02T18:13:18', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'b8937d0f-c446-40ea-9809-b20729d0493f' User entered 'None (0)' | System           | 02 Nov 2020 23:13:33 |
|  | System           | 02 Nov 2020 23:13:33 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:32**

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-02T18:13:19', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'b8937d0f-c446-40ea-9809-b20729d0493f' User entered 'None (0)' | System           | 02 Nov 2020 23:13:33 |
|  | System           | 02 Nov 2020 23:13:33 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:32**

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-02T18:13:21', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'b8937d0f-c446-40ea-9809-b20729d0493f' User entered 'None (0)' | System           | 02 Nov 2020 23:13:33 |
|  | System           | 02 Nov 2020 23:13:33 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:32**

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-02T18:13:23', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'b8937d0f-c446-40ea-9809-b20729d0493f' User entered 'None (0)' | System           | 02 Nov 2020 23:13:33 |
|  | System           | 02 Nov 2020 23:13:33 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:32**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-02T18:13:25', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'b8937d0f-c446-40ea-9809-b20729d0493f' User entered 'None (0)' | System           | 02 Nov 2020 23:13:33 |
|  | System           | 02 Nov 2020 23:13:33 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:32**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-02T18:13:27', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'b8937d0f-c446-40ea-9809-b20729d0493f' User entered 'None (0)' | System           | 02 Nov 2020 23:13:33 |
|  | System           | 02 Nov 2020 23:13:33 |



**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:32**

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-02T18:13:29', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'b8937d0f-c446-40ea-9809-b20729d0493f' User entered 'No (N)' | System           | 02 Nov 2020 23:13:33 |
|  | System           | 02 Nov 2020 23:13:33 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-11-02T18:13:31', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'b8937d0f-c446-40ea-9809-b20729d0493f' User entered '02 Nov 2020 18:13' | System           | 02 Nov 2020 23:13:33 |
|   | System           | 02 Nov 2020 23:13:33 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '02 Nov 2020 12:00' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:13:32**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 03:09:17 |
| User entered '03 Nov 2020 11:59' | System           | 27 Oct 2020 15:02:21 |

**US3602123**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

[Was Contact Attempted?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 20 Nov 2020 18:59:43 |

**US3602123**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '3 Nov 2020' | (b) (4)<br>(b) (4), (b) (6) | 20 Nov 2020 18:59:43 |

**US3602123**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.                  | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>(b) (4), (b) (6) | 20 Nov 2020 18:59:43 |

**US3602123**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 20 Nov 2020 18:59:43 |



**US3602123**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:32**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 20 Nov 2020 18:59:53 |

**US3602123**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:32**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered 'I'  | System           | 20 Nov 2020 18:59:53 |

**US3602123**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

[Was Contact Attempted?](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.                                 | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)' reason for change: New Information | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 16:54:19 |
| User entered 'No (N)'                                     | (b) (4), (b) (6)            | 23 Nov 2020 17:22:42 |

**US3602123**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.                                     | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '10 Nov 2020' reason for change: New Information | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 16:54:19 |
| User entered empty.   | (b) (4), (b) (6)            | 23 Nov 2020 17:22:42 |

**US3602123**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)     | 14 Apr 2021 12:26:08 |
| User signature succeeded.                  | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)              | 29 Mar 2021 16:54:19 |
| reason for change: New Information         | (b) (4), (b) (6)     |                      |
| User entered empty.                        | (b) (4), (b) (6)     | 23 Nov 2020 17:22:42 |

**US3602123**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 17:22:42 |

**US3602123**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:32**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 20 Nov 2020 19:15:46 |

**US3602123**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:32**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered 'I'  | System           | 20 Nov 2020 19:15:46 |



**US3602123**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

[Was Contact Attempted?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 20 Nov 2020 19:17:19 |

**US3602123**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '17 Nov 2020' | (b) (4)<br>(b) (4), (b) (6) | 20 Nov 2020 19:17:19 |

**US3602123**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.                  | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>(b) (4), (b) (6) | 20 Nov 2020 19:17:19 |

**US3602123**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 20 Nov 2020 19:17:19 |

**US3602123**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:32**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 20 Nov 2020 19:17:26 |

**US3602123**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:32**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered 'I'  | System           | 20 Nov 2020 19:17:26 |

**US3602123**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:32**

[Was this visit performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 30 Nov 2020 14:47:57 |

**US3602123**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:32**

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '24 Nov 2020' | (b) (4)<br>(b) (4), (b) (6) | 30 Nov 2020 14:47:57 |



**US3602123**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:32**

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.      | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>(b) (4), (b) (6) | 30 Nov 2020 14:47:57 |

**US3602123**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:32**

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered 'VISIT3' | System           | 30 Nov 2020 14:47:57 |

**US3602123**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[Were vital signs assessed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 30 Nov 2020 14:48:49 |

**US3602123**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

**Date of assessment** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '24 Nov 2020' | (b) (4)<br>(b) (4), (b) (6) | 30 Nov 2020 14:48:49 |

**US3602123**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

**Time of assessment (00:00-23:59)**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '08:30'      | (b) (4)<br>(b) (4), (b) (6) | 30 Nov 2020 14:48:49 |

**US3602123**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered '24 Nov 2020 08:30' | System           | 30 Nov 2020 14:48:49 |

**US3602123**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[Temperature \(xxx.x\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '97.3' F     | (b) (4)<br>(b) (4), (b) (6) | 30 Nov 2020 14:48:49 |

**US3602123**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[Route of measurement](#)

| Audit                        | User                        | Time (GMT)           |
|------------------------------|-----------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.    | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Other (Other)' | (b) (4)<br>(b) (4), (b) (6) | 30 Nov 2020 14:48:49 |



**US3602123**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[If Other, specify](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.                         | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Temporal/Forehead scanner was used' | (b) (4)<br>(b) (4), (b) (6) | 30 Nov 2020 14:48:49 |

**US3602123**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[Pulse \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '79'         | (b) (4)<br>(b) (4), (b) (6) | 30 Nov 2020 14:48:49 |

**US3602123**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered 'bpm' | System           | 30 Nov 2020 14:48:49 |

**US3602123**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '16'         | (b) (4)<br>(b) (4), (b) (6) | 30 Nov 2020 14:48:49 |

**US3602123**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered 'breaths/min' | System           | 30 Nov 2020 14:48:49 |

**US3602123**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '136'        | (b) (4)<br>(b) (4), (b) (6) | 30 Nov 2020 14:48:49 |

**US3602123**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered 'mmHg' | System           | 30 Nov 2020 14:48:49 |

**US3602123**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '79'         | (b) (4)<br>(b) (4), (b) (6) | 30 Nov 2020 14:48:49 |



**US3602123**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered 'mmHg' | System           | 30 Nov 2020 14:48:49 |

**US3602123**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[Height \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
|                   |                  |                      |

**US3602123**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[Weight \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |

**US3602123**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:13:32**

[Was the physical examination performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 30 Nov 2020 14:49:02 |

**US3602123**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:13:32**

**Date of examination (dd MMM yyyy)**

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '24 Nov 2020' | (b) (4)<br>(b) (4), (b) (6) | 30 Nov 2020 14:49:02 |

**US3602123**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:32**

[Was the sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 30 Nov 2020 14:49:16 |

**US3602123**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:32**

**Collection date** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '24 Nov 2020' | (b) (4)<br>(b) (4), (b) (6) | 30 Nov 2020 14:49:16 |

**US3602123**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:32**

[Collection time \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '08:30'      | (b) (4)<br>(b) (4), (b) (6) | 30 Nov 2020 14:49:16 |



**US3602123**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:32**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered '24 Nov 2020 08:30' | System           | 30 Nov 2020 14:49:16 |

**US3602123**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:32**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 30 Nov 2020 14:49:22 |

**US3602123**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:32**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered '1'  | System           | 30 Nov 2020 14:49:22 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 61' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-12-01T08:29:18', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'bd5a7275-71be-4f91-8149-c07a61dedca2' | System | 01 Dec 2020 13:29:33 |
| User entered 'No (N)'  | System | 01 Dec 2020 13:29:33 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-12-01T08:29:23', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'bd5a7275-71be-4f91-8149-c07a61dedca2' | System | 01 Dec 2020 13:29:33 |
| User entered 'No (N)'  | System | 01 Dec 2020 13:29:33 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-12-01T08:29:29', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'bd5a7275-71be-4f91-8149-c07a61dedca2' User entered '01 Dec 2020 08:29:29' | System | 01 Dec 2020 13:29:33 |
|  | System | 01 Dec 2020 13:29:33 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '29 Nov 2020 00:01' | System | 20 Nov 2020 11:35:32 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '03 Dec 2020 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 68' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-12-08T18:29:18', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '99832964-0d33-4263-b9d7-c60f7bd80e0e' User entered 'No (N)' | System | 08 Dec 2020 23:29:33 |
|  | System | 08 Dec 2020 23:29:33 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-12-08T18:29:23', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '99832964-0d33-4263-b9d7-c60f7bd80e0e' User entered 'No (N)' | System | 08 Dec 2020 23:29:33 |
|  | System | 08 Dec 2020 23:29:33 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6213EE99-E3D1-493A-84B8-6CC8A12A17C2)', Time: '2020-12-08T18:29:29', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '99832964-0d33-4263-b9d7-c60f7bd80e0e' User entered '08 Dec 2020 18:29:29' | System | 08 Dec 2020 23:29:33 |
|  | System | 08 Dec 2020 23:29:33 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '06 Dec 2020 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '10 Dec 2020 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 75' | System | 20 Nov 2020 11:35:32 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '13 Dec 2020 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '17 Dec 2020 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 82' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2020-12-21T11:52:20', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '9d7f835b-2d79-4084-b9a3-02e3d4b1c940' | System | 21 Dec 2020 16:52:29 |
| User entered 'No (N)'  | System | 21 Dec 2020 16:52:29 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2020-12-21T11:52:23', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '9d7f835b-2d79-4084-b9a3-02e3d4b1c940' | System | 21 Dec 2020 16:52:29 |
| User entered 'No (N)'  | System | 21 Dec 2020 16:52:29 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2020-12-21T11:52:26', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '9d7f835b-2d79-4084-b9a3-02e3d4b1c940' User entered '21 Dec 2020 11:52:26' | System | 21 Dec 2020 16:52:29 |
|  | System | 21 Dec 2020 16:52:29 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '20 Dec 2020 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '24 Dec 2020 23:59' | System | 20 Nov 2020 11:35:32 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 89' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2020-12-29T12:00:23', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'af34a665-4dbf-4648-ace5-9702a47b2bd5' User entered 'No (N)' | System | 29 Dec 2020 17:00:36 |
|  | System | 29 Dec 2020 17:00:36 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2020-12-29T12:00:26', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'af34a665-4dbf-4648-ace5-9702a47b2bd5' User entered 'No (N)' | System | 29 Dec 2020 17:00:36 |
|  | System | 29 Dec 2020 17:00:36 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2020-12-29T12:00:30', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'af34a665-4dbf-4648-ace5-9702a47b2bd5' User entered '29 Dec 2020 12:00:30' | System | 29 Dec 2020 17:00:36 |
|  | System | 29 Dec 2020 17:00:36 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '27 Dec 2020 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '31 Dec 2020 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 96' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-01-05T12:19:04', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'a7e8d53b-f13a-4b63-a032-48f6f17224e2' | System | 05 Jan 2021 17:19:14 |
| User entered 'No (N)'  | System | 05 Jan 2021 17:19:14 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-01-05T12:19:07', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'a7e8d53b-f13a-4b63-a032-48f6f17224e2' | System | 05 Jan 2021 17:19:14 |
| User entered 'No (N)'  | System | 05 Jan 2021 17:19:14 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-01-05T12:19:11', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'a7e8d53b-f13a-4b63-a032-48f6f17224e2' User entered '05 Jan 2021 12:19:11' | System | 05 Jan 2021 17:19:14 |
|  | System | 05 Jan 2021 17:19:14 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '03 Jan 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '07 Jan 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 103' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-01-12T16:33:34', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '2096477c-ef5c-49b7-86d9-41090a8071d2' User entered 'No (N)' | System | 12 Jan 2021 21:33:43 |
|  | System | 12 Jan 2021 21:33:43 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-01-12T16:33:37', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '2096477c-ef5c-49b7-86d9-41090a8071d2' | System | 12 Jan 2021 21:33:43 |
| User entered 'No (N)'  | System | 12 Jan 2021 21:33:43 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-01-12T16:33:40', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '2096477c-ef5c-49b7-86d9-41090a8071d2' User entered '12 Jan 2021 16:33:40' | System | 12 Jan 2021 21:33:43 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '10 Jan 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '14 Jan 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 110' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-01-20T17:59:28', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '00f7a40c-ccd5-43fe-acb4-9ece96ca2e0b' User entered 'No (N)' | System | 20 Jan 2021 22:59:52 |
|  | System | 20 Jan 2021 22:59:52 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-01-20T17:59:46', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '00f7a40c-ccd5-43fe-acb4-9ece96ca2e0b' User entered 'No (N)' | System | 20 Jan 2021 22:59:52 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-01-20T17:59:49', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '00f7a40c-ccd5-43fe-acb4-9ece96ca2e0b' User entered '20 Jan 2021 17:59:49' | System | 20 Jan 2021 22:59:52 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '17 Jan 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '21 Jan 2021 23:59' | System | 20 Nov 2020 11:35:32 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 117' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-01-26T17:39:00', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'f9f35acb-6759-4ced-bb1b-786a96482c74' User entered 'No (N)' | System | 27 Jan 2021 00:33:25 |
|  | System | 27 Jan 2021 00:33:25 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-01-26T17:39:04', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'f9f35acb-6759-4ced-bb1b-786a96482c74' | System | 27 Jan 2021 00:33:25 |
| User entered 'No (N)'  | System | 27 Jan 2021 00:33:25 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-01-26T17:39:08', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'f9f35acb-6759-4ced-bb1b-786a96482c74' User entered '26 Jan 2021 17:39:08' | System | 27 Jan 2021 00:33:25 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '24 Jan 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '28 Jan 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 124' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-02-04T10:19:49', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'cf2330ba-f240-46ee-9a50-3d4920c4bcf3' | System | 04 Feb 2021 14:20:08 |
| User entered 'No (N)'  | System | 04 Feb 2021 14:20:08 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-02-04T10:19:52', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'cf2330ba-f240-46ee-9a50-3d4920c4bcf3' | System | 04 Feb 2021 14:20:08 |
| User entered 'No (N)'  | System | 04 Feb 2021 14:20:08 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-02-04T10:19:55', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'cf2330ba-f240-46ee-9a50-3d4920c4bcf3' | System | 04 Feb 2021 14:20:08 |
| User entered '04 Feb 2021 10:19:55'  | System | 04 Feb 2021 14:20:08 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '31 Jan 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '04 Feb 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 131' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-02-09T12:28:07', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '4ed4747e-70f6-4118-afe4-5922519ddfec' User entered 'Yes (Y)' | System | 09 Feb 2021 17:28:46 |
|   | System | 09 Feb 2021 17:28:46 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-02-09T12:28:11', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '4ed4747e-70f6-4118-afe4-5922519ddfec' | System | 09 Feb 2021 17:28:46 |
| User entered 'No (N)'  | System | 09 Feb 2021 17:28:46 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-02-09T12:28:16', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '4ed4747e-70f6-4118-afe4-5922519ddfec' User entered 'No (N)' | System | 09 Feb 2021 17:28:46 |
|  | System | 09 Feb 2021 17:28:46 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-02-09T12:28:28', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '4ed4747e-70f6-4118-afe4-5922519ddfec' User entered 'Yes (Y)' | System | 09 Feb 2021 17:28:46 |
|   | System | 09 Feb 2021 17:28:46 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Please 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 (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-02-09T12:28:32', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '4ed4747e-70f6-4118-afe4-5922519ddfec' | System | 09 Feb 2021 17:28:46 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)'   | System | 09 Feb 2021 17:28:46 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-02-09T12:28:34', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '4ed4747e-70f6-4118-afe4-5922519ddfec' | System | 09 Feb 2021 17:28:46 |
| User entered '09 Feb 2021 12:28:34'  | System | 09 Feb 2021 17:28:46 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '07 Feb 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '11 Feb 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 138' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-02-17T18:00:46', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '255b3de0-8369-40f2-9248-431ab096398a' User entered 'No (N)' | System | 17 Feb 2021 23:02:58 |
|  | System | 17 Feb 2021 23:02:58 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-02-17T18:00:49', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '255b3de0-8369-40f2-9248-431ab096398a' User entered 'No (N)' | System | 17 Feb 2021 23:02:58 |
|  | System | 17 Feb 2021 23:02:58 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-02-17T18:00:52', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '255b3de0-8369-40f2-9248-431ab096398a' User entered '17 Feb 2021 18:00:52' | System | 17 Feb 2021 23:02:58 |
|  | System | 17 Feb 2021 23:02:58 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '14 Feb 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '18 Feb 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 145' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-02-22T11:26:19', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '8bc36089-cea1-4e3b-a165-d9c8136799d7' User entered 'No (N)' | System | 22 Feb 2021 16:26:40 |
|  | System | 22 Feb 2021 16:26:40 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-02-22T11:26:29', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '8bc36089-cea1-4e3b-a165-d9c8136799d7' User entered 'No (N)' | System | 22 Feb 2021 16:26:40 |
|  | System | 22 Feb 2021 16:26:40 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-02-22T11:26:35', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '8bc36089-cea1-4e3b-a165-d9c8136799d7' | System | 22 Feb 2021 16:26:40 |
| User entered '22 Feb 2021 11:26:35'  | System | 22 Feb 2021 16:26:40 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '21 Feb 2021 00:01' | System | 20 Nov 2020 11:35:32 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '25 Feb 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 152' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '28 Feb 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '04 Mar 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 159' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-03-07T10:03:19-05:00', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '5a86e5e8-5878-4f72-a45a-8ed27f46d593' | System | 07 Mar 2021 15:03:27 |
| User entered 'No (N)'  | System | 07 Mar 2021 15:03:27 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-03-07T10:03:22-05:00', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '5a86e5e8-5878-4f72-a45a-8ed27f46d593' | System | 07 Mar 2021 15:03:27 |
| User entered 'No (N)'  | System | 07 Mar 2021 15:03:27 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-03-07T10:03:25-05:00', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '5a86e5e8-5878-4f72-a45a-8ed27f46d593' User entered '07 Mar 2021 10:03:25' | System | 07 Mar 2021 15:03:27 |
|  | System | 07 Mar 2021 15:03:27 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '07 Mar 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '11 Mar 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 166' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-03-15T06:31:55-04:00', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '12d69af1-4ab1-496e-955e-7cd8d2d6f5b6' | System | 15 Mar 2021 10:32:02 |
| User entered 'No (N)'  | System | 15 Mar 2021 10:32:02 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-03-15T06:31:58-04:00', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '12d69af1-4ab1-496e-955e-7cd8d2d6f5b6' | System | 15 Mar 2021 10:32:02 |
| User entered 'No (N)'  | System | 15 Mar 2021 10:32:02 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-03-15T06:32:00-04:00', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '12d69af1-4ab1-496e-955e-7cd8d2d6f5b6' | System | 15 Mar 2021 10:32:02 |
| User entered '15 Mar 2021 06:32:00'  | System | 15 Mar 2021 10:32:02 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '14 Mar 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '18 Mar 2021 23:59' | System | 20 Nov 2020 11:35:32 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 173' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-03-21T09:25:13-04:00', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '4758aa07-4781-40f7-ba06-640172e23ee4' User entered 'No (N)' | System | 21 Mar 2021 13:25:21 |
|  | System | 21 Mar 2021 13:25:21 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-03-21T09:25:16-04:00', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '4758aa07-4781-40f7-ba06-640172e23ee4' | System | 21 Mar 2021 13:25:21 |
| User entered 'No (N)'  | System | 21 Mar 2021 13:25:21 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-03-21T09:25:18-04:00', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '4758aa07-4781-40f7-ba06-640172e23ee4' User entered '21 Mar 2021 09:25:18' | System | 21 Mar 2021 13:25:21 |
|  | System | 21 Mar 2021 13:25:21 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '21 Mar 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '25 Mar 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 180' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-03-30T12:15:46-04:00', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '4e8f922f-4d5f-4f8a-b12e-318708976d75' | System | 30 Mar 2021 16:19:08 |
| User entered 'No (N)'  | System | 30 Mar 2021 16:19:08 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-03-30T12:15:48-04:00', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '4e8f922f-4d5f-4f8a-b12e-318708976d75' | System | 30 Mar 2021 16:19:08 |
| User entered 'No (N)'  | System | 30 Mar 2021 16:19:08 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-03-30T12:15:50-04:00', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '4e8f922f-4d5f-4f8a-b12e-318708976d75' | System | 30 Mar 2021 16:19:08 |
| User entered '30 Mar 2021 12:15:50'  | System | 30 Mar 2021 16:19:08 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '28 Mar 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '01 Apr 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 187' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-04-05T13:34:21-04:00', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '03aaf059-6d45-411f-a714-0d891ff33d45' | System | 08 Apr 2021 14:38:45 |
| User entered 'No (N)'  | System | 08 Apr 2021 14:38:45 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-04-05T13:34:24-04:00', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '03aaf059-6d45-411f-a714-0d891ff33d45' | System | 08 Apr 2021 14:38:45 |
| User entered 'No (N)'  | System | 08 Apr 2021 14:38:45 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-04-05T13:34:28-04:00', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '03aaf059-6d45-411f-a714-0d891ff33d45' | System | 08 Apr 2021 14:38:45 |
| User entered '05 Apr 2021 13:34:28'  | System | 08 Apr 2021 14:38:45 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '04 Apr 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '08 Apr 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 194' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-04-13T12:00:53-04:00', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '7d236251-7e82-445c-a5be-c2548db82b94' | System | 13 Apr 2021 16:03:39 |
| User entered 'No (N)'  | System | 13 Apr 2021 16:03:39 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-04-13T12:00:58-04:00', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '7d236251-7e82-445c-a5be-c2548db82b94' | System | 13 Apr 2021 16:03:39 |
| User entered 'No (N)'  | System | 13 Apr 2021 16:03:39 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-04-13T12:01:01-04:00', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '7d236251-7e82-445c-a5be-c2548db82b94' | System | 13 Apr 2021 16:03:39 |
| User entered '13 Apr 2021 12:01:01'  | System | 13 Apr 2021 16:03:39 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '11 Apr 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '15 Apr 2021 23:59' | System | 20 Nov 2020 11:35:32 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 201' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-04-21T17:59:13-04:00', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '35740b22-801a-4e25-9256-78256a7fe912' | System | 21 Apr 2021 21:59:40 |
| User entered 'No (N)'  | System | 21 Apr 2021 21:59:40 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-04-21T17:59:15-04:00', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '35740b22-801a-4e25-9256-78256a7fe912' | System | 21 Apr 2021 21:59:40 |
| User entered 'No (N)'  | System | 21 Apr 2021 21:59:40 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-04-21T17:59:30-04:00', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '35740b22-801a-4e25-9256-78256a7fe912' | System | 21 Apr 2021 21:59:40 |
| User entered '21 Apr 2021 17:59:30'  | System | 21 Apr 2021 21:59:40 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '18 Apr 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '22 Apr 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 208' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-04-29T12:00:04-04:00', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'c87b3d77-4383-4b12-b36c-d1c930ebf0e1' User entered 'No (N)' | System | 29 Apr 2021 16:00:14 |
|  | System | 29 Apr 2021 16:00:14 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-04-29T12:00:07-04:00', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'c87b3d77-4383-4b12-b36c-d1c930ebf0e1' User entered 'No (N)' | System | 29 Apr 2021 16:00:14 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-04-29T12:00:10-04:00', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: 'c87b3d77-4383-4b12-b36c-d1c930ebf0e1' | System | 29 Apr 2021 16:00:14 |
| User entered '29 Apr 2021 12:00:10'  | System | 29 Apr 2021 16:00:14 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '25 Apr 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '29 Apr 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 215' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-05-03T08:54:39-04:00', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '3a9d1632-716b-4aa1-ada1-8427f1487c90' | System | 03 May 2021 12:54:47 |
| User entered 'No (N)'  | System | 03 May 2021 12:54:47 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-05-03T08:54:41-04:00', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '3a9d1632-716b-4aa1-ada1-8427f1487c90' | System | 03 May 2021 12:54:47 |
| User entered 'No (N)'  | System | 03 May 2021 12:54:47 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-05-03T08:54:44-04:00', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '3a9d1632-716b-4aa1-ada1-8427f1487c90' | System | 03 May 2021 12:54:47 |
| User entered '03 May 2021 08:54:44'  | System | 03 May 2021 12:54:47 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '02 May 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '06 May 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 222' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '09 May 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '13 May 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 229' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '16 May 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '20 May 2021 23:59' | System | 20 Nov 2020 11:35:32 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 236' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '23 May 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '27 May 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 243' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '30 May 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '03 Jun 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 250' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '06 Jun 2021 00:01' | System | 20 Nov 2020 11:35:32 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '10 Jun 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 257' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '13 Jun 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '17 Jun 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 264' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '20 Jun 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '24 Jun 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 271' | System | 20 Nov 2020 11:35:32 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '27 Jun 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '01 Jul 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 278' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '04 Jul 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '08 Jul 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 285' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '11 Jul 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '15 Jul 2021 23:59' | System | 20 Nov 2020 11:35:32 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 292' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '18 Jul 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '22 Jul 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 299' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '25 Jul 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '29 Jul 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 306' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '01 Aug 2021 00:01' | System | 20 Nov 2020 11:35:32 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '05 Aug 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 313' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '08 Aug 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '12 Aug 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 320' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '15 Aug 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '19 Aug 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 327' | System | 20 Nov 2020 11:35:32 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '22 Aug 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '26 Aug 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 334' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '29 Aug 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '02 Sep 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 341' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '05 Sep 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '09 Sep 2021 23:59' | System | 20 Nov 2020 11:35:32 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 348' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '12 Sep 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '16 Sep 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 355' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '19 Sep 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '23 Sep 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 362' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '26 Sep 2021 00:01' | System | 20 Nov 2020 11:35:32 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '30 Sep 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 369' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '03 Oct 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '07 Oct 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 376' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '10 Oct 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '14 Oct 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 383' | System | 20 Nov 2020 11:35:32 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '17 Oct 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '21 Oct 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 390' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '24 Oct 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '28 Oct 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 397' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '31 Oct 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '04 Nov 2021 23:59' | System | 20 Nov 2020 11:35:32 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 404' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '07 Nov 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '11 Nov 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 411' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '14 Nov 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '18 Nov 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 418' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '21 Nov 2021 00:01' | System | 20 Nov 2020 11:35:32 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '25 Nov 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 425' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '28 Nov 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '02 Dec 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 432' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '05 Dec 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '09 Dec 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 439' | System | 20 Nov 2020 11:35:32 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '12 Dec 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '16 Dec 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 446' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '19 Dec 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '23 Dec 2021 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 453' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '26 Dec 2021 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '30 Dec 2021 23:59' | System | 20 Nov 2020 11:35:32 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 460' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '02 Jan 2022 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '06 Jan 2022 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 467' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '09 Jan 2022 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '13 Jan 2022 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 474' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '16 Jan 2022 00:01' | System | 20 Nov 2020 11:35:32 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '20 Jan 2022 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 481' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '23 Jan 2022 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '27 Jan 2022 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 488' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '30 Jan 2022 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '03 Feb 2022 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 495' | System | 20 Nov 2020 11:35:32 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '06 Feb 2022 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '10 Feb 2022 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 502' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '13 Feb 2022 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '17 Feb 2022 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 509' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '20 Feb 2022 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '24 Feb 2022 23:59' | System | 20 Nov 2020 11:35:32 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 516' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '27 Feb 2022 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '03 Mar 2022 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 523' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '06 Mar 2022 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '10 Mar 2022 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 530' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '13 Mar 2022 00:01' | System | 20 Nov 2020 11:35:32 |



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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '17 Mar 2022 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 537' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '20 Mar 2022 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '24 Mar 2022 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 544' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '27 Mar 2022 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '31 Mar 2022 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 551' | System | 20 Nov 2020 11:35:32 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '03 Apr 2022 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '07 Apr 2022 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 558' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '10 Apr 2022 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '14 Apr 2022 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 565' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '17 Apr 2022 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '21 Apr 2022 23:59' | System | 20 Nov 2020 11:35:32 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 572' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '24 Apr 2022 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '28 Apr 2022 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 579' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '01 May 2022 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '05 May 2022 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 586' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '08 May 2022 00:01' | System | 20 Nov 2020 11:35:32 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '12 May 2022 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 593' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '15 May 2022 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '19 May 2022 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 600' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '22 May 2022 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '26 May 2022 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 607' | System | 20 Nov 2020 11:35:32 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '29 May 2022 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '02 Jun 2022 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 614' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '05 Jun 2022 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '09 Jun 2022 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 621' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '12 Jun 2022 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '16 Jun 2022 23:59' | System | 20 Nov 2020 11:35:32 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 628' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '19 Jun 2022 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '23 Jun 2022 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 635' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '26 Jun 2022 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '30 Jun 2022 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 642' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '03 Jul 2022 00:01' | System | 20 Nov 2020 11:35:32 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '07 Jul 2022 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 649' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '10 Jul 2022 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '14 Jul 2022 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 656' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '17 Jul 2022 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '21 Jul 2022 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 663' | System | 20 Nov 2020 11:35:32 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '24 Jul 2022 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '28 Jul 2022 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 670' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '31 Jul 2022 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '04 Aug 2022 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 677' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '07 Aug 2022 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '11 Aug 2022 23:59' | System | 20 Nov 2020 11:35:32 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 684' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '14 Aug 2022 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '18 Aug 2022 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 691' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '21 Aug 2022 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '25 Aug 2022 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 698' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '28 Aug 2022 00:01' | System | 20 Nov 2020 11:35:32 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '01 Sep 2022 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 705' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '04 Sep 2022 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '08 Sep 2022 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 712' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '11 Sep 2022 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '15 Sep 2022 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 719' | System | 20 Nov 2020 11:35:32 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '18 Sep 2022 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '22 Sep 2022 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 726' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '25 Sep 2022 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '29 Sep 2022 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 733' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '02 Oct 2022 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '06 Oct 2022 23:59' | System | 20 Nov 2020 11:35:32 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 740' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '09 Oct 2022 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '13 Oct 2022 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 747' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '16 Oct 2022 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '20 Oct 2022 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 754' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '23 Oct 2022 00:01' | System | 20 Nov 2020 11:35:32 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '27 Oct 2022 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 761' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '30 Oct 2022 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '03 Nov 2022 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 768' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '06 Nov 2022 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '10 Nov 2022 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 775' | System | 20 Nov 2020 11:35:32 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '13 Nov 2022 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '17 Nov 2022 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 782' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '20 Nov 2022 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '24 Nov 2022 23:59' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 789' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '27 Nov 2022 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '01 Dec 2022 23:59' | System | 20 Nov 2020 11:35:32 |



**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered 'Day 796' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '04 Dec 2022 00:01' | System | 20 Nov 2020 11:35:32 |

**US3602123**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:13:32**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 11:35:32 |
| Amendment Manager: User entered '08 Dec 2022 23:59' | System | 20 Nov 2020 11:35:32 |

US3602123

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:13:32

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Apr 2021 15:16:30 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-03-05T15:05:48-05:00', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '48f702a3-ef2b-474b-9b7d-c4e8c9bc13bb' | System           | 05 Mar 2021 20:05:53 |
| User entered 'No (N)'  | System           | 05 Mar 2021 20:05:53 |

**US3602123**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Date & Time of Submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Apr 2021 15:16:30 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D4BF8EAA-4D38-4523-988D-B486FF258DFC)', Time: '2021-03-05T15:05:51-05:00', User OID: 'PatientReportedOutcome (US3602123)', ODM File OID: '48f702a3-ef2b-474b-9b7d-c4e8c9bc13bb' User entered '05 Mar 2021 15:05:51' | System           | 05 Mar 2021 20:05:53 |
|  | System           | 05 Mar 2021 20:05:53 |

**US3602123**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

[Was Contact Attempted?](#)

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)     | 14 Apr 2021 12:26:08 |
| User signature succeeded.                                      | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)' reason for change: Per Query Resolution | (b) (4), (b) (6)     | 31 Mar 2021 13:16:48 |
| User entered 'No (N)' reason for change: Per Query Resolution  | (b) (4), (b) (6)     | 05 Jan 2021 21:55:36 |
| User entered 'Yes (Y)'   | (b) (4), (b) (6)     | 05 Jan 2021 21:54:10 |

US3602123

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:13:32

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '22 Dec 2020' reason for change: Data Entry Error   | (b) (4)<br>(b) (4), (b) (6) | 31 Mar 2021 13:16:48 |
| User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).             | System                      | 05 Jan 2021 21:55:36 |
| Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System). | System                      | 05 Jan 2021 21:55:36 |
| User entered empty; reason for change Per Query Resolution   | (b) (4), (b) (6)            | 05 Jan 2021 21:55:36 |
| User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).             | System                      | 05 Jan 2021 21:54:10 |
| User entered '26 Dec 2020'   | (b) (4), (b) (6)            | 05 Jan 2021 21:54:10 |

**US3602123**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

[Please select one status for the follow-up contact](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded.   | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Contact Made (CONTACT MADE)'<br>reason for change: Data Entry Error | (b) (4)<br>(b) (4), (b) (6) | 31 Mar 2021 13:16:48 |
| User entered empty; reason for change Data Entry<br>Error                         | (b) (4), (b) (6)            | 05 Jan 2021 21:55:36 |
| User entered 'Contact Made (CONTACT MADE)'  | (b) (4), (b) (6)            | 05 Jan 2021 21:54:10 |



**US3602123**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 05 Jan 2021 21:54:10 |

**US3602123**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:32**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 12:26:08 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 05 Jan 2021 21:56:31 |

**US3602123**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:32**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 12:26:08 |
| User entered 'I'  | System           | 05 Jan 2021 21:56:31 |

**US3602123**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

[Was Contact Attempted?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 11:46:35 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 03 Mar 2021 05:56:07 |

**US3602123**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 11:46:35 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 03 Mar 2021 05:56:07 |

**US3602123**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

[Please select one status for the follow-up contact](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 11:46:35 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 03 Mar 2021 05:56:07 |

US3602123

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:13:32

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 28 Apr 2021 11:46:35 |
| User signature succeeded.   | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Missed SC due to lack of clarity concerning EUA protocol for combining Part A + B SC. Understanding was Part A SC resume after Part B. Following clarification, SC schedule changes implemented.' reason for change: Data Entry Error | (b) (4)<br>(b) (4), (b) (6) | 31 Mar 2021 13:15:25 |
| User entered empty.   | (b) (4), (b) (6)            | 03 Mar 2021 05:56:07 |

**US3602123**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:32**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 11:46:35 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 03 Mar 2021 05:56:12 |



**US3602123**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:32**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 11:46:35 |
| User entered 'I'  | System           | 03 Mar 2021 05:56:12 |

**US3602123**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

[Was Contact Attempted?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 11:46:35 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 03 Mar 2021 05:57:22 |

**US3602123**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 11:46:35 |
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '24 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 03 Mar 2021 05:57:22 |

**US3602123**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 28 Apr 2021 11:46:35 |
| User signature succeeded.                  | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>(b) (4), (b) (6) | 03 Mar 2021 05:57:22 |

**US3602123**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 11:46:35 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 03 Mar 2021 05:57:22 |

**US3602123**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:32**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 11:46:35 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 03 Mar 2021 05:57:44 |

**US3602123**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:32**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 11:46:35 |
| User entered 'I'  | System           | 03 Mar 2021 05:57:44 |

**US3602123**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

[Was Contact Attempted?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 11:46:35 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 26 Mar 2021 20:28:46 |



**US3602123**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 11:46:35 |
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '26 Mar 2021' | (b) (4)<br>(b) (4), (b) (6) | 26 Mar 2021 20:28:46 |

**US3602123**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 28 Apr 2021 11:46:35 |
| User signature succeeded.                  | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>(b) (4), (b) (6) | 26 Mar 2021 20:28:46 |

**US3602123**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 11:46:35 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Mar 2021 20:28:46 |

**US3602123**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:32**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 11:46:35 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 26 Mar 2021 20:29:12 |

**US3602123**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:32**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 11:46:35 |
| User entered 'I'  | System           | 26 Mar 2021 20:29:12 |

**US3602123**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:32**

[Was this visit performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 02 May 2021 01:32:35 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 27 Apr 2021 13:31:18 |

**US3602123**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:32**

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 02 May 2021 01:32:35 |
| User entered '26 Apr 2021' | (b) (4)<br>(b) (4), (b) (6) | 27 Apr 2021 13:31:18 |

**US3602123**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:32**

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Bindu Balani (b) (4)        | 02 May 2021 01:32:35 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>(b) (4), (b) (6) | 27 Apr 2021 13:31:18 |



**US3602123**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:32**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT4' | System | 27 Apr 2021 13:31:18 |

**US3602123**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[Were vital signs assessed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 02 May 2021 01:32:35 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 27 Apr 2021 13:36:03 |

**US3602123**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

**Date of assessment** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 02 May 2021 01:32:35 |
| User entered '26 Apr 2021' | (b) (4)<br>(b) (4), (b) (6) | 27 Apr 2021 13:36:03 |

**US3602123**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

**Time of assessment (00:00-23:59)**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 02 May 2021 01:32:35 |
| User entered '08:20'      | (b) (4)<br>(b) (4), (b) (6) | 27 Apr 2021 13:36:03 |

**US3602123**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Apr 2021 08:20' | System | 27 Apr 2021 13:36:03 |

US3602123

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:13:32

Temperature (xxx.x)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.   | Bindu Balani (b) (4)        | 02 May 2021 01:32:35 |
| User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).          | (b) (4)<br>(b) (4), (b) (6) | 29 Apr 2021 04:06:29 |
| Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS.' (Site from System). | (b) (4), (b) (6)            | 27 Apr 2021 13:36:10 |
| User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).          | System                      | 27 Apr 2021 13:36:03 |
| User entered '96.2' F   | (b) (4), (b) (6)            | 27 Apr 2021 13:36:03 |

**US3602123**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[Route of measurement](#)

| Audit                        | User                 | Time (GMT)           |
|------------------------------|----------------------|----------------------|
| User signature succeeded.    | Bindu Balani (b) (4) | 02 May 2021 01:32:35 |
|                              | (b) (4)              |                      |
| User entered 'Other (Other)' | (b) (4), (b) (6)     | 27 Apr 2021 13:36:03 |
|                              |                      |                      |

**US3602123**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[If Other, specify](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.                         | Bindu Balani (b) (4)        | 02 May 2021 01:32:35 |
| User entered 'Temporal/Forehead scanner was used' | (b) (4)<br>(b) (4), (b) (6) | 27 Apr 2021 13:36:03 |



**US3602123**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[Pulse \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 02 May 2021 01:32:35 |
| User entered '74'         | (b) (4)<br>(b) (4), (b) (6) | 27 Apr 2021 13:36:03 |

**US3602123**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 27 Apr 2021 13:36:03 |

**US3602123**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 02 May 2021 01:32:35 |
| User entered '20'         | (b) (4)<br>(b) (4), (b) (6) | 27 Apr 2021 13:36:03 |

**US3602123**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 27 Apr 2021 13:36:03 |

**US3602123**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 02 May 2021 01:32:35 |
| User entered '126'        | (b) (4)<br>(b) (4), (b) (6) | 27 Apr 2021 13:36:03 |

**US3602123**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 27 Apr 2021 13:36:03 |

**US3602123**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 02 May 2021 01:32:35 |
| User entered '87'         | (b) (4)<br>(b) (4), (b) (6) | 27 Apr 2021 13:36:03 |

**US3602123**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 27 Apr 2021 13:36:03 |



**US3602123**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:13:32**

[Was the physical examination performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 02 May 2021 01:32:35 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 27 Apr 2021 13:34:31 |

**US3602123**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:13:32**

**Date of examination (dd MMM yyyy)**

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 02 May 2021 01:32:35 |
| User entered '26 Apr 2021' | (b) (4)<br>(b) (4), (b) (6) | 27 Apr 2021 13:34:31 |

**US3602123**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:32**

[Was the sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 02 May 2021 01:32:35 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 27 Apr 2021 13:34:55 |

**US3602123**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:32**

**Collection date** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 02 May 2021 01:32:35 |
| User entered '26 Apr 2021' | (b) (4)<br>(b) (4), (b) (6) | 27 Apr 2021 13:34:55 |

**US3602123**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:32**

[Collection time \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 02 May 2021 01:32:35 |
| User entered '08:30'      | (b) (4)<br>(b) (4), (b) (6) | 27 Apr 2021 13:34:55 |

**US3602123**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:32**

[Collection date and time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '26 Apr 2021 08:30' | System | 27 Apr 2021 13:34:55 |

US3602123

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:13:32

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 02 May 2021 01:32:35 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 27 Apr 2021 13:36:29 |

**US3602123**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:32**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 27 Apr 2021 13:36:29 |



**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:32**

[Was this visit performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 01:57:22 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:32**

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '12 Jan 2021' | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 01:57:22 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:32**

[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 06:33:38 |
| User signature succeeded.      | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 01:57:22 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:32**

[Folder OID](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 28 Apr 2021 06:33:38 |
| User entered 'UNBLND_DECIDE' | System           | 13 Jan 2021 01:57:22 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:13:32**

[Date of updated informed consent \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '12 Jan 2021' | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 01:57:47 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:13:32**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

| Audit                                      | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)     | 28 Apr 2021 06:33:38 |
| User signature succeeded.                  | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
| User entered '0' WR# 5295537               | (b) (4)              | 10 Mar 2021 16:55:28 |
| Amendment Manager inserted this DataPoint. | System               | 06 Mar 2021 09:39:50 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:13:32**

[Was the participant unblinded?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 01:57:47 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:13:32**

[Under what version of the Protocol was the Participant unblinded?](#)

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)     | 28 Apr 2021 06:33:38 |
| User signature succeeded.   | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
| User entered 'AMENDMENT 6 OR LATER<br>(AMENDMENT 6 OR LATER)' WR# 5295537 | (b) (4)<br>System    | 10 Mar 2021 16:55:28 |
| Amendment Manager inserted this DataPoint.                                | System               | 06 Mar 2021 09:39:50 |



**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:13:32**

**Date of unblinding** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '12 Jan 2021' | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 01:57:47 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:13:32**

[Participant randomization assignment](#)

| Audit                            | User                        | Time (GMT)           |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded.        | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Placebo (Placebo)' | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 01:57:47 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:13:32**

[Actual Dose 1](#)

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| Data hard locked.                                   | (b) (4), (b) (6)     | 28 Apr 2021 06:33:38 |
| User signature succeeded.                           | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
| Amendment Manager: User entered 'Placebo (Placebo)' | (b) (4)              | 20 Jan 2021 09:50:26 |
| User entered 'Placebo (Placebo)'                    | (b) (4), (b) (6)     | 13 Jan 2021 01:57:47 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:13:32**

[Actual Dose 2](#)

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| Data hard locked.                                   | (b) (4), (b) (6)     | 28 Apr 2021 06:33:38 |
| User signature succeeded.                           | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
| Amendment Manager: User entered 'Placebo (Placebo)' | (b) (4)              | 20 Jan 2021 09:50:26 |
| User entered 'Placebo (Placebo)'                    | (b) (4), (b) (6)     | 13 Jan 2021 01:57:47 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:13:32**

[Will participant receive mRNA-1273?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 01:57:47 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:13:32**

[Placebo Only Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 06:33:38 |
| User entered '1'  | System           | 13 Jan 2021 01:57:47 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:13:32**

[Continuing with mRNA-1273](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 06:33:38 |
| User entered 'I'  | System           | 13 Jan 2021 01:57:47 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:13:32**

[Height](#)

| Audit                                    | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded.                | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered missing code ND - Not Done. | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:03:32 |



**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:13:32**

[Weight](#)

| Audit                                    | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded.                | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered missing code ND - Not Done. | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:03:32 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:13:32**

**BMI (xxx.x)**

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 28 Apr 2021 06:33:38 |
| User entered empty.       | System           | 13 Jan 2021 02:03:32 |
| DataPoint set to visible. | System           | 13 Jan 2021 01:57:47 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:13:32**

[Height](#)

| Audit                                    | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded.                | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered missing code ND - Not Done. | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:03:32 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:13:32**

[Weight](#)

| Audit                                    | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded.                | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered missing code ND - Not Done. | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:03:32 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:13:32**

[BMI \(xxx.x\)](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 28 Apr 2021 06:33:38 |
| User entered empty.       | System           | 13 Jan 2021 02:03:32 |
| DataPoint set to visible. | System           | 13 Jan 2021 01:57:47 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Timepoint](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.                                | (b) (4), (b) (6) | 28 Apr 2021 06:33:38 |
| User accepted default value 'Pre-Dose (PREDOSE)' | (b) (4), (b) (6) | 13 Jan 2021 02:03:32 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Were vital signs assessed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:03:32 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

**Date of assessment** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '12 Jan 2021' | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:03:32 |



**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Time of assessment \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '14:00'      | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:03:32 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 06:33:38 |
| User entered '12 Jan 2021 14:00' | System           | 13 Jan 2021 02:03:32 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Temperature \(xxx.x\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '97.2' F     | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:03:32 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Route of measurement](#)

| Audit                        | User                        | Time (GMT)           |
|------------------------------|-----------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded.    | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Other (Other)' | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:03:32 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[If Other, specify](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded.                         | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Temporal/Forehead scanner was used' | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:03:32 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Pulse \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '83'         | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:03:32 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 28 Apr 2021 06:33:38 |
| User entered 'bpm' | System           | 13 Jan 2021 02:03:32 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '16'         | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:03:32 |



**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 28 Apr 2021 06:33:38 |
| User entered 'breaths/min' | System           | 13 Jan 2021 02:03:32 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '131'        | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:03:32 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 06:33:38 |
| User entered 'mmHg' | System           | 13 Jan 2021 02:03:32 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '85'         | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:03:32 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 06:33:38 |
| User entered 'mmHg' | System           | 13 Jan 2021 02:03:32 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:13:32**

[Height](#)

| Audit                                    | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded.                | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered missing code ND - Not Done. | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:03:32 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:13:32**

[Weight](#)

| Audit                                    | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded.                | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered missing code ND - Not Done. | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:03:32 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:13:32**

[BMI \(xxx.x\)](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 28 Apr 2021 06:33:38 |
| User entered empty.       | System           | 13 Jan 2021 02:03:32 |
| DataPoint set to visible. | System           | 13 Jan 2021 01:57:47 |



**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Timepoint](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6) | 28 Apr 2021 06:33:38 |
| User accepted default value 'Post-Dose (POSTDOSE)' | (b) (4), (b) (6) | 13 Jan 2021 02:03:32 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Were vital signs assessed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:03:32 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

**Date of assessment** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '12 Jan 2021' | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:03:32 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Time of assessment \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '16:55'      | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:03:32 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 06:33:38 |
| User entered '12 Jan 2021 16:55' | System           | 13 Jan 2021 02:03:32 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Temperature \(xxx.x\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '97.6' F     | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:03:32 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Route of measurement](#)

| Audit                        | User                        | Time (GMT)           |
|------------------------------|-----------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded.    | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Other (Other)' | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:03:32 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[If Other, specify](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded.                         | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Temporal/Forehead scanner was used' | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:03:32 |



**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Pulse \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '83'         | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:03:32 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 28 Apr 2021 06:33:38 |
| User entered 'bpm' | System           | 13 Jan 2021 02:03:32 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '16'         | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:03:32 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 28 Apr 2021 06:33:38 |
| User entered 'breaths/min' | System           | 13 Jan 2021 02:03:32 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '134'        | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:03:32 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 06:33:38 |
| User entered 'mmHg' | System           | 13 Jan 2021 02:03:32 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '77'         | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:03:32 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 06:33:38 |
| User entered 'mmHg' | System           | 13 Jan 2021 02:03:32 |



**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:13:32**

[Was the physical examination performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 01:58:02 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:13:32**

**Date of examination (dd MMM yyyy)**

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '12 Jan 2021' | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 01:58:02 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:13:32**

[Was the pregnancy test performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:00:11 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:13:32**

**Date of test (dd MMM yyyy)**

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '12 Jan 2021' | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:00:11 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:13:32**

[Test performed](#)

| Audit                        | User                        | Time (GMT)           |
|------------------------------|-----------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded.    | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Urine (URINE)' | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:00:11 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:13:32**

[Result](#)

| Audit                              | User                        | Time (GMT)           |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded.          | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Negative (NEGATIVE)' | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:00:11 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:13:32**

[Was FSH sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:00:11 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:13:32**

[Collection date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:00:11 |



**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:13:32**

[Collection time](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:00:11 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:13:32**

[Collection date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 06:33:38 |
| User entered empty. | System           | 13 Jan 2021 02:00:11 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:32**

[Was study treatment given?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:01:05 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:32**

[If No, reason not given](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:01:05 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:32**

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:01:05 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:32**

[What was the study treatment? \(Unblinded\)](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 28 Apr 2021 06:33:38 |
| User entered 'mRNA-1273'  | System           | 13 Jan 2021 02:01:05 |
| DataPoint set to visible. | System           | 13 Jan 2021 01:57:47 |

US3602123

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:13:32

What was the treatment date? (dd MMM yyyy)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| Query 'Per dosing sheets and progress note, this date is 13Jan2021. Verify and update data. ' canceled (Site from CRA).    | (b) (4)<br>(b) (4), (b) (6) | 04 Mar 2021 23:23:40 |
| User opened query 'Per dosing sheets and progress note, this date is 13Jan2021. Verify and update data. ' (Site from CRA). | (b) (4), (b) (6)            | 04 Mar 2021 23:23:25 |
| User entered '12 Jan 2021'   | (b) (4), (b) (6)            | 13 Jan 2021 02:01:05 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:32**

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '16:25'      | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:01:05 |



**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:32**

[Treatment Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 06:33:38 |
| User entered '12 Jan 2021 16:25' | System           | 13 Jan 2021 02:01:05 |

US3602123

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:13:32

[Which arm was used to give treatment?](#)

| Audit                              | User                        | Time (GMT)           |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded.          | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:01:05 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:32**

[What was the frequency of the study treatment dosing?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 06:33:38 |
| User entered 'ONCE' | System           | 13 Jan 2021 02:01:05 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:32**

[What was the route of administration for the study treatment?](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 28 Apr 2021 06:33:38 |
| User entered 'INTRAMUSCULAR' | System           | 13 Jan 2021 02:01:05 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:32**

[Was the sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:01:29 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:32**

**Collection date** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '12 Jan 2021' | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:01:29 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:32**

[Collection time \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '13:45'      | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:01:29 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:32**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 06:33:38 |
| User entered '12 Jan 2021 13:45' | System           | 13 Jan 2021 02:01:29 |



**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:13:32**

[Was the sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:01:41 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:13:32**

**Collection date** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '12 Jan 2021' | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:01:41 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:13:32**

**Collection time (00:00 - 23:59)**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '13:50'      | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:01:41 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:13:32**

[Collection Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 06:33:38 |
| User entered '12 Jan 2021 13:50' | System           | 13 Jan 2021 02:01:41 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:32**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 06:33:38 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 02:03:38 |

**US3602123**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:32**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 06:33:38 |
| User entered '1'  | System           | 13 Jan 2021 02:03:38 |

**US3602123**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

[Was Contact Attempted?](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 30 Apr 2021 18:01:37 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)     | 25 Jan 2021 22:38:16 |
|                           |                      |                      |

**US3602123**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

| Audit                      | User                 | Time (GMT)           |
|----------------------------|----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)     | 30 Apr 2021 18:01:37 |
|                            |                      |                      |
| User signature succeeded.  | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                            | (b) (4)              |                      |
| User entered '19 Jan 2021' | (b) (4), (b) (6)     | 25 Jan 2021 22:38:16 |
|                            |                      |                      |



**US3602123**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)     | 30 Apr 2021 18:01:37 |
| User signature succeeded.                  | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6)     | 25 Jan 2021 22:38:16 |

**US3602123**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 30 Apr 2021 18:01:37 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered empty.       | (b) (4), (b) (6)     | 25 Jan 2021 22:38:16 |
|                           |                      |                      |

**US3602123**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:32**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)     | 30 Apr 2021 18:01:37 |
|                           |                      |                      |
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
|                           | (b) (4)              |                      |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)     | 25 Jan 2021 22:38:27 |
|                           |                      |                      |

**US3602123**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:32**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 18:01:37 |
|                   |                  |                      |
| User entered 'I'  | System           | 25 Jan 2021 22:38:27 |

**US3602123**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:32**

[OLD29 Placebo Flag](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 30 Apr 2021 18:01:37 |
|                           |                  |                      |
| User entered 'I'          | System           | 25 Jan 2021 22:38:27 |
| DataPoint set to visible. | System           | 25 Jan 2021 22:38:27 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:32**

[Was this visit performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:58:57 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:53:32 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:32**

[Visit date \(dd MMM yyyy\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:58:57 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered '9 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:53:32 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:32**

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)            | 30 Apr 2021 17:58:57 |
| User signature succeeded.      | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:53:32 |



**US3602123**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:32**

[Folder OID](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 30 Apr 2021 17:58:57 |
| User entered 'OLD29' | System           | 10 Feb 2021 20:53:32 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Timepoint](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.                                | (b) (4), (b) (6) | 30 Apr 2021 17:58:57 |
| User accepted default value 'Pre-Dose (PREDOSE)' | (b) (4), (b) (6) | 10 Feb 2021 21:11:00 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Were vital signs assessed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:58:57 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:11:00 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

**Date of assessment** (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:58:57 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered '9 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:11:00 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

**Time of assessment (00:00-23:59)**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:58:57 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered '14:10'      | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:11:00 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Vital Signs Date and Time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 30 Apr 2021 17:58:57 |
| User entered '9 Feb 2021 14:10' | System           | 10 Feb 2021 21:11:00 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Temperature \(xxx.x\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:58:57 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered '96.9' F     | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:11:00 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Route of measurement](#)

| Audit                        | User                        | Time (GMT)           |
|------------------------------|-----------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)            | 30 Apr 2021 17:58:57 |
| User signature succeeded.    | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered 'Other (Other)' | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:11:00 |



**US3602123**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[If Other, specify](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6)            | 30 Apr 2021 17:58:57 |
| User signature succeeded.                         | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered 'Temporal/Forehead scanner was used' | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:11:00 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Pulse \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:58:57 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered '76'         | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:11:00 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 30 Apr 2021 17:58:57 |
| User entered 'bpm' | System           | 10 Feb 2021 21:11:00 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:58:57 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered '16'         | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:11:00 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 30 Apr 2021 17:58:57 |
| User entered 'breaths/min' | System           | 10 Feb 2021 21:11:00 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:58:57 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered '136'        | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:11:00 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 17:58:57 |
| User entered 'mmHg' | System           | 10 Feb 2021 21:11:00 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:58:57 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered '76'         | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:11:00 |



**US3602123**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 17:58:57 |
| User entered 'mmHg' | System           | 10 Feb 2021 21:11:00 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Timepoint](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6) | 30 Apr 2021 17:58:57 |
| User accepted default value 'Post-Dose (POSTDOSE)' | (b) (4), (b) (6) | 10 Feb 2021 21:11:00 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Were vital signs assessed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:58:57 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:11:00 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

**Date of assessment** (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:58:57 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered '9 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:11:00 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

**Time of assessment (00:00-23:59)**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:58:57 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered '16:37'      | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:11:00 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Vital Signs Date and Time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 30 Apr 2021 17:58:57 |
| User entered '9 Feb 2021 16:37' | System           | 10 Feb 2021 21:11:00 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Temperature \(xxx.x\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:58:57 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered '97.7' F     | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:11:00 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Route of measurement](#)

| Audit                        | User                        | Time (GMT)           |
|------------------------------|-----------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)            | 30 Apr 2021 17:58:57 |
| User signature succeeded.    | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered 'Other (Other)' | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:11:00 |



**US3602123**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[If Other, specify](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6)            | 30 Apr 2021 17:58:57 |
| User signature succeeded.                         | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered 'Temporal/Forehead scanner was used' | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:11:00 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Pulse \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:58:57 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered '69'         | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:11:00 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 30 Apr 2021 17:58:57 |
| User entered 'bpm' | System           | 10 Feb 2021 21:11:00 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:58:57 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered '18'         | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:11:00 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 30 Apr 2021 17:58:57 |
| User entered 'breaths/min' | System           | 10 Feb 2021 21:11:00 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:58:57 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered '120'        | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:11:00 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 17:58:57 |
| User entered 'mmHg' | System           | 10 Feb 2021 21:11:00 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:58:57 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered '85'         | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:11:00 |



**US3602123**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 17:58:57 |
| User entered 'mmHg' | System           | 10 Feb 2021 21:11:00 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:13:32**

[Was the physical examination performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:58:57 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:06:48 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:13:32**

**Date of examination (dd MMM yyyy)**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:58:57 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered '9 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:06:48 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:13:32**

[Was the pregnancy test performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:58:57 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:08:38 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:13:32**

**Date of test (dd MMM yyyy)**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:58:57 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered '9 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:08:38 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:13:32**

[Test performed](#)

| Audit                        | User                        | Time (GMT)           |
|------------------------------|-----------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)            | 30 Apr 2021 17:58:57 |
| User signature succeeded.    | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered 'Urine (URINE)' | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:08:38 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:13:32**

[Result](#)

| Audit                              | User                        | Time (GMT)           |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)            | 30 Apr 2021 17:58:57 |
| User signature succeeded.          | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered 'Negative (NEGATIVE)' | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:08:38 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:13:32**

[Was FSH sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:58:57 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:08:38 |



**US3602123**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:13:32**

[Collection date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:58:57 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:08:38 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:13:32**

[Collection time](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:58:57 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:08:38 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:13:32**

[Collection date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 17:58:57 |
| User entered empty. | System           | 10 Feb 2021 21:08:38 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:32**

[Was study treatment given?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:58:57 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 11 Feb 2021 22:07:44 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:32**

[If No, reason not given](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:58:57 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 11 Feb 2021 22:07:44 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:32**

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:58:57 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 11 Feb 2021 22:07:44 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:32**

[What was the study treatment? \(Unblinded\)](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 30 Apr 2021 17:58:57 |
| User entered 'mRNA-1273'  | System           | 11 Feb 2021 22:07:44 |
| DataPoint set to visible. | System           | 25 Jan 2021 22:38:27 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:32**

[What was the treatment date? \(dd MMM yyyy\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:58:57 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered '9 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 11 Feb 2021 22:07:44 |



**US3602123**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:32**

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:58:57 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered '16:07'      | (b) (4)<br>(b) (4), (b) (6) | 11 Feb 2021 22:07:44 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:32**

[Treatment Date and Time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 30 Apr 2021 17:58:57 |
| User entered '9 Feb 2021 16:07' | System           | 11 Feb 2021 22:07:44 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:32**

[Which arm was used to give treatment?](#)

| Audit                              | User                        | Time (GMT)           |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)            | 30 Apr 2021 17:58:57 |
| User signature succeeded.          | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4)<br>(b) (4), (b) (6) | 11 Feb 2021 22:07:44 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:32**

[What was the frequency of the study treatment dosing?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 17:58:57 |
| User entered 'ONCE' | System           | 11 Feb 2021 22:07:44 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:13:32**

[What was the route of administration for the study treatment?](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 30 Apr 2021 17:58:57 |
| User entered 'INTRAMUSCULAR' | System           | 11 Feb 2021 22:07:44 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:32**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 17:58:57 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:12:19 |

**US3602123**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:32**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:58:57 |
| User entered 'I'  | System           | 10 Feb 2021 21:12:19 |

**US3602123**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

[Was Contact Attempted?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 08:01:17 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 20:03:43 |



**US3602123**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 08:01:17 |
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '18 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 20:03:43 |

**US3602123**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:13:32**

[Please select one status for the follow-up contact](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6)            | 30 Apr 2021 08:01:17 |
| User signature succeeded.                          | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Contact Not Made (CONTACT NOT MADE)' | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 20:03:43 |

US3602123

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:13:32

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)     | 30 Apr 2021 08:01:17 |
| User signature succeeded.   | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
| User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.  | (b) (4) System       | 18 Feb 2021 20:04:01 |
| Please review and reconcile.' (Site from System).   |                      |                      |
| User entered 'Attempted to reach subject for Day 36 OL Part B safety call. Calls made on 2/16 and 2/17. No answer. Left a message to call back study team' reason for change: New Information | (b) (4), (b) (6)     | 18 Feb 2021 20:04:01 |
| User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.  | System               | 18 Feb 2021 20:03:43 |
| Please review and reconcile.' (Site from System).   |                      |                      |
| User entered empty.   | (b) (4), (b) (6)     | 18 Feb 2021 20:03:43 |

**US3602123**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:32**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 08:01:17 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 20:04:07 |

**US3602123**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:13:32**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:01:17 |
| User entered 'I'  | System           | 18 Feb 2021 20:04:07 |

**US3602123**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:32**

[Was this visit performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 03:58:21 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 04:54:09 |

**US3602123**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:32**

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 03:58:21 |
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered '10 Mar 2021' | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 04:54:09 |

**US3602123**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:32**

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)            | 30 Apr 2021 03:58:21 |
| User signature succeeded.      | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 04:54:09 |



**US3602123**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:13:32**

[Folder OID](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 30 Apr 2021 03:58:21 |
| User entered 'OLD57' | System           | 11 Mar 2021 04:54:09 |

**US3602123**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[Were vital signs assessed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 03:58:21 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 04:55:32 |

**US3602123**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

**Date of assessment** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 03:58:21 |
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '10 Mar 2021' | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 04:55:32 |

**US3602123**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

**Time of assessment (00:00-23:59)**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 03:58:21 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '08:20'      | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 04:55:32 |

**US3602123**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 30 Apr 2021 03:58:21 |
| User entered '10 Mar 2021 08:20' | System           | 11 Mar 2021 04:55:32 |

**US3602123**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[Temperature \(xxx.x\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 03:58:21 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '97.2' F     | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 04:55:32 |

**US3602123**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[Route of measurement](#)

| Audit                        | User                        | Time (GMT)           |
|------------------------------|-----------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)            | 30 Apr 2021 03:58:21 |
| User signature succeeded.    | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Other (Other)' | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 04:55:32 |

**US3602123**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[If Other, specify](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6)            | 30 Apr 2021 03:58:21 |
| User signature succeeded.                         | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'Temporal/Forehead scanner was used' | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 04:55:32 |



**US3602123**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[Pulse \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 03:58:21 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '71'         | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 04:55:32 |

**US3602123**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 30 Apr 2021 03:58:21 |
| User entered 'bpm' | System           | 11 Mar 2021 04:55:32 |

**US3602123**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 03:58:21 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '18'         | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 04:55:32 |

**US3602123**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 30 Apr 2021 03:58:21 |
| User entered 'breaths/min' | System           | 11 Mar 2021 04:55:32 |

**US3602123**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 03:58:21 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '133'        | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 04:55:32 |

**US3602123**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 03:58:21 |
| User entered 'mmHg' | System           | 11 Mar 2021 04:55:32 |

**US3602123**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 03:58:21 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered '74'         | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 04:55:32 |

**US3602123**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 03:58:21 |
| User entered 'mmHg' | System           | 11 Mar 2021 04:55:32 |



**US3602123**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[Height \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 03:58:21 |
|                   |                  |                      |

**US3602123**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:13:32**

[Weight \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 03:58:21 |

**US3602123**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:13:32**

[Was the physical examination performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 03:58:21 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 04:55:44 |

**US3602123**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:13:32**

**Date of examination (dd MMM yyyy)**

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 03:58:21 |
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered '10 Mar 2021' | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 04:55:44 |

**US3602123**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:32**

[Was the sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 03:58:21 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 04:56:03 |

**US3602123**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:32**

**Collection date** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 03:58:21 |
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered '10 Mar 2021' | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 04:56:03 |

**US3602123**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:32**

[Collection time \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 03:58:21 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered '08:40'      | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 04:56:03 |

**US3602123**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:13:32**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 30 Apr 2021 03:58:21 |
| User entered '10 Mar 2021 08:40' | System           | 11 Mar 2021 04:56:03 |



US3602123

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:13:32

[Did the participant experience any adverse events?](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 03 May 2021 08:46:18 |
| User signature succeeded.   | Bindu Balani (b) (4)        | 19 Mar 2021 17:45:26 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:27:29 |
| User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of HEADACHE persist beyond Day 7 (start date: Day 1 - 02Oct2020; end date: Day 8 - 09Oct2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.<br>' (Site from DM).   | (b) (4), (b) (6)            | 08 Feb 2021 17:01:34 |
| Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of HEADACHE persist beyond Day 7 (start date: Day 1 - 02Oct2020; end date: Day 8 - 09Oct2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.<br>' answered with 'After reviewing the protocol, symptom does not meet AE reporting criteria as per notes.' (Site from DM). | (b) (4), (b) (6)            | 05 Feb 2021 19:59:07 |
| User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of HEADACHE persist beyond Day 7 (start date: Day 1 - 02Oct2020; end date: Day 8 - 09Oct2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.<br>' (Site from DM).   | (b) (4), (b) (6)            | 05 Feb 2021 14:08:46 |
| User entered 'Yes (Y)'  | (b) (4), (b) (6)            | 27 Oct 2020 15:18:43 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:32**

[AEID](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:32:15 |

US3602123

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:13:32

[Adverse event](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                | 28 Apr 2021 20:32:15 |
| User signature succeeded.  | Bindu Balani (b) (4)            | 13 Mar 2021 23:41:58 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)     | 11 Mar 2021 15:21:03 |
| User closed query 'Per CDM: "To help clarify the clinical significance of the event (Injection site ...)an possible association with the administration of investigational product and/or study procedure, if this event is related to the site of administration, please update the Adverse Event to "Injection site (discomfort, pain, swelling, nodule, mass, irritation, bruising, rash, dermatitis)." (Site from DM). Query 'Per CDM: "To help clarify the clinical significance of the event (Injection site ...)and possible association with the administration of investigational product and/or study procedure, if this event is related to the site of administration, please update the Adverse Event to "Injection site (discomfort, pain, swelling, nodule, mass, irritation, bruising, rash, dermatitis)." answered with 'Per source, this "Shoulder pain_ L sided", is ongoing and was present before the vaccine. A.E is NOT related to the administration of IP and/or study procedure. Thank you.' (Site from DM). | (b) (4), (b) (6)                | 10 Feb 2021 02:43:18 |
| User opened query 'Per CDM: "To help clarify the clinical significance of the event (Injection site ...)an possible association with the administration of investigational product and/or study procedure, if this event is related to the site of administration, please update the Adverse Event to "Injection site (discomfort, pain, swelling, nodule, mass, irritation, bruising, rash, dermatitis)." (Site from DM).   | (b) (4), (b) (6)                | 08 Feb 2021 20:51:40 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Musculoskeletal pain, LLT: Shoulder pain - version MedDRA\23.0.  | Coder Import (b) (4)<br>(b) (4) | 08 Feb 2021 03:02:36 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.   | Coder Import (b) (4)<br>(b) (4) | 27 Oct 2020 23:04:29 |

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EAB) (1725)

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**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:32**

[Adverse event](#)

| Audit                                  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data point term sent to Coder          | System           | 27 Oct 2020 15:34:22 |
| User entered 'Shoulder pain _ L sided' | (b) (4), (b) (6) | 27 Oct 2020 15:33:57 |
|  |                  |                      |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:32**

[Was this a medically-attended AE?](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 28 Apr 2021 20:32:15 |
| User signature succeeded.                                 | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.                                       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered 'Yes (Y)' reason for change: New Information | (b) (4), (b) (6)            | 19 Jan 2021 16:57:06 |
| User entered 'No (N)'                                     | (b) (4), (b) (6)            | 27 Oct 2020 15:33:57 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:32**

[Was this a Solicited Adverse Reaction?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:15 |
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 27 Oct 2020 15:33:57 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:32**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:15 |
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 27 Oct 2020 15:33:57 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:32**

[Start date \(dd MMM yyyy\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:15 |
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered '9 Oct 2020' | (b) (4), (b) (6)            | 27 Oct 2020 15:33:57 |



US3602123

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:13:32

Start time (00:00-23:59)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 28 Apr 2021 20:32:15 |
| User signature succeeded.   | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).  | (b) (4), (b) (6)            | 28 Oct 2020 03:42:34 |
| Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'Info acquired from EMR, inserted as such' (Site from System). | (b) (4), (b) (6)            | 27 Oct 2020 15:34:14 |
| User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).  | System                      | 27 Oct 2020 15:33:57 |
| User entered '07:00'  | (b) (4), (b) (6)            | 27 Oct 2020 15:33:57 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:32**

[AE start date and time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 28 Apr 2021 20:32:15 |
| User entered '9 Oct 2020 07:00' | System           | 27 Oct 2020 15:33:57 |

US3602123

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:13:32

[Ongoing?](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 28 Apr 2021 20:32:15 |
| User signature succeeded.   | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered 'No (N)' reason for change: New Information  | (b) (4), (b) (6)            | 08 Mar 2021 21:30:57 |
| User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an end date should be recorded. Please review and update as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).  | (b) (4), (b) (6)            | 15 Jan 2021 15:42:29 |
| Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an end date should be recorded. Please review and update as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'A.E still ongoing per source and PI.' (Site from DM). | (b) (4), (b) (6)            | 13 Jan 2021 15:55:28 |
| User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an end date should be recorded. Please review and update as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).  | (b) (4), (b) (6)            | 06 Jan 2021 13:52:25 |
| User entered 'Yes (Y)'  | (b) (4), (b) (6)            | 27 Oct 2020 15:33:57 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:32**

*If not Ongoing, end date (dd MMM yyyy)*

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 28 Apr 2021 20:32:15 |
| User signature succeeded.                                     | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered '19 Feb 2021' reason for change: New Information | (b) (4), (b) (6)            | 08 Mar 2021 21:30:57 |
| User entered empty.   | (b) (4), (b) (6)            | 27 Oct 2020 15:33:57 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:32**

**End time (00:00-23:59)**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:15 |
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered empty.       | (b) (4), (b) (6)            | 27 Oct 2020 15:33:57 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:32**

[AE End Date and Time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 20:32:15 |
| User entered empty. | System           | 27 Oct 2020 15:33:57 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:32**

[Severity](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 28 Apr 2021 20:32:15 |
| User signature succeeded.  | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)'<br>reason for change: New Information | (b) (4), (b) (6)            | 19 Jan 2021 16:57:06 |
| User entered 'Grade 1/Mild (Grade 1/Mild)'   | (b) (4), (b) (6)            | 27 Oct 2020 15:33:57 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:32**

[Is the adverse event serious?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:15 |
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 27 Oct 2020 15:33:57 |



**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:32**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:15 |
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered '0'          | (b) (4), (b) (6)            | 27 Oct 2020 15:33:57 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:32**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:15 |
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered '0'          | (b) (4), (b) (6)            | 27 Oct 2020 15:33:57 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:32**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:15 |
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered '0'          | (b) (4), (b) (6)            | 27 Oct 2020 15:33:57 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:32**

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:15 |
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered empty.       | (b) (4), (b) (6)            | 27 Oct 2020 15:33:57 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:32**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:15 |
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered empty.       | (b) (4), (b) (6)            | 27 Oct 2020 15:33:57 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:32**

[Admitted to ICU?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:15 |
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered empty.       | (b) (4), (b) (6)            | 27 Oct 2020 15:33:57 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:32**

[Number of Days in ICU](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:15 |
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered empty.       | (b) (4), (b) (6)            | 27 Oct 2020 15:33:57 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:32**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:15 |
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered '0'          | (b) (4), (b) (6)            | 27 Oct 2020 15:33:57 |



**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:32**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:15 |
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered '0'          | (b) (4), (b) (6)            | 27 Oct 2020 15:33:57 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:32**

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:15 |
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered '0'          | (b) (4), (b) (6)            | 27 Oct 2020 15:33:57 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:32**

[Relationship to investigational product](#)

| Audit                            | User                        | Time (GMT)           |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6)            | 28 Apr 2021 20:32:15 |
| User signature succeeded.        | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.              | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered 'Related (RELATED)' | (b) (4), (b) (6)            | 27 Oct 2020 15:33:57 |

US3602123

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:13:32

[Relationship to Study Procedure](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 28 Apr 2021 20:32:15 |
| User signature succeeded.   | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User closed query 'Per CDM: Response noted. Please confirm the Relationship to Study Procedure once again and update it appropriately. Else clarify. Thank you. ' (Site from DM).                                       | (b) (4), (b) (6)            | 23 Nov 2020 03:28:32 |
| Query 'Per CDM: Response noted. Please confirm the Relationship to Study Procedure once again and update it appropriately. Else clarify. Thank you. ' answered with 'Updated per EMR notes by provider' (Site from DM). | (b) (4), (b) (6)            | 20 Nov 2020 18:35:50 |
| User entered 'Related (RELATED)' reason for change: New Information   | (b) (4), (b) (6)            | 20 Nov 2020 18:35:23 |
| User opened query 'Per CDM: Response noted. Please confirm the Relationship to Study Procedure once again and update it appropriately. Else clarify. Thank you. ' (Site from DM).                                       | (b) (4), (b) (6)            | 12 Nov 2020 14:37:13 |
| User closed query 'Data is required. Please complete.' (Site from System).  | (b) (4), (b) (6)            | 29 Oct 2020 13:46:19 |
| Query 'Data is required. Please complete.' answered with 'Nothing was selected for this per EMR' (Site from System).  | (b) (4), (b) (6)            | 27 Oct 2020 15:34:42 |
| User opened query 'Data is required. Please complete.' (Site from System).  | System                      | 27 Oct 2020 15:33:57 |
| User entered empty.   | (b) (4), (b) (6)            | 27 Oct 2020 15:33:57 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:32**

[Action taken with investigational product](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 20:32:15 |
| User signature succeeded.  | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered 'None (NONE)' | (b) (4), (b) (6)            | 27 Oct 2020 15:33:57 |

US3602123

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:13:32

None

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 28 Apr 2021 20:32:15 |
| User signature succeeded.  | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User closed query 'Other action taken is missing.<br>Please check at least one action from the options<br>provided.' (Site from System). | System                      | 27 Oct 2020 15:34:44 |
| User entered '1' reason for change: Data Entry Error   | (b) (4), (b) (6)            | 27 Oct 2020 15:34:44 |
| User opened query 'Other action taken is missing.<br>Please check at least one action from the options<br>provided.' (Site from System). | System                      | 27 Oct 2020 15:33:57 |
| User entered '0'   | (b) (4), (b) (6)            | 27 Oct 2020 15:33:57 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:32**

[Concomitant Medication](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:15 |
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered '0'          | (b) (4), (b) (6)            | 27 Oct 2020 15:33:57 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:32**

[Concomitant Procedure](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:15 |
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered '0'          | (b) (4), (b) (6)            | 27 Oct 2020 15:33:57 |



**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:32**

[Outcome](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 28 Apr 2021 20:32:15 |
| User signature succeeded.   | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information                 | (b) (4), (b) (6)            | 08 Mar 2021 21:30:57 |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: New Information | (b) (4), (b) (6)            | 20 Nov 2020 18:37:11 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'  | (b) (4), (b) (6)            | 27 Oct 2020 15:33:57 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:32**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:15 |
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered empty.       | (b) (4), (b) (6)            | 27 Oct 2020 15:33:57 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:32**

[Narrative](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:15 |
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered empty.       | (b) (4), (b) (6)            | 27 Oct 2020 15:33:57 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:32**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:32:15 |
| User entered '0'  | System           | 27 Oct 2020 15:33:57 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:32**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:32:15 |
| User entered '1'  | System           | 19 Jan 2021 16:57:06 |
| User entered '0'  | System           | 27 Oct 2020 15:33:57 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:13:32**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:32:15 |
|                   |                  |                      |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:13:32**

[AEID](#)

| Audit                                 | User                 | Time (GMT)           |
|---------------------------------------|----------------------|----------------------|
| User signature succeeded.             | Bindu Balani (b) (4) | 13 Mar 2021 23:41:58 |
| DataPoint Verified.                   | (b) (4)              |                      |
|                                       | (b) (4), (b) (6)     | 18 Feb 2021 18:33:06 |
| Reviewed for Safety.                  | (b) (4), (b) (6)     | 17 Feb 2021 14:54:59 |
| User entered                          | System               | 17 Feb 2021 14:54:54 |
| 'USA-US079-2021-mRNA-1273-P301000002' |                      |                      |
| User entered 'New'                    | (b) (4), (b) (6)     | 17 Feb 2021 14:54:54 |
|                                       |                      |                      |

US3602123

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:13:32

[Adverse event](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| User signature succeeded.   | Bindu Balani (b) (4)            | 05 Apr 2021 21:29:37 |
| User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of IMMUNE THROMBOCYTOPENIA. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).                       | (b) (4)<br>(b) (4), (b) (6)     | 22 Mar 2021 15:31:16 |
| User coded data point as SOC: Blood and lymphatic system disorders, HLT: Platelet disorders, HLT: Thrombocytopenias, PT: Immune thrombocytopenia, LLT: Immune thrombocytopenia - version MedDRA\23.0.   | Coder Import (b) (4)<br>(b) (4) | 21 Mar 2021 19:03:27 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.  | Coder Import (b) (4)<br>(b) (4) | 21 Mar 2021 19:03:27 |
| Data point term sent to Coder   | System                          | 19 Mar 2021 21:54:26 |
| Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of IMMUNE THROMBOCYTOPENIA. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' answered with 'Updated A.E Term.' (Site from DM). | (b) (4), (b) (6)                | 19 Mar 2021 21:54:08 |
| Coding entries removed.   | (b) (4), (b) (6)                | 19 Mar 2021 21:53:59 |
| User entered 'Worsening of IMMUNE THROMBOCYTOPENIA' reason for change: Per Query Resolution   | (b) (4), (b) (6)                | 19 Mar 2021 21:53:59 |
| User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of IMMUNE THROMBOCYTOPENIA. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).                       | (b) (4), (b) (6)                | 18 Mar 2021 23:33:00 |
| User coded data point as SOC: Blood and lymphatic system disorders, HLT: Platelet disorders, HLT: Thrombocytopenias, PT: Immune thrombocytopenia, LLT: Immune thrombocytopenia - version MedDRA\23.0.   | Coder Import (b) (4)<br>(b) (4) | 17 Mar 2021 02:13:34 |



US3602123

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:13:32

[Adverse event](#)

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4) | 17 Mar 2021 02:13:34 |
| Data point term sent to Coder   | (b) (4)              | 17 Mar 2021 02:12:17 |
| Query 'For coding purposes, please split ITP WITH SIGNIFICANT DROP OF THE PLATELET  | Coder Import (b) (4) | 17 Mar 2021 02:11:35 |
| COUNT into separate entries. 1. ITP (spell out abbreviation) and 2. SIGNIFICANT DROP OF THE PLATELET COUNT' canceled (Site from System).  | (b) (4)              |                      |
| User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Platelet disorders, HLT: Thrombocytopenias, PT: Immune thrombocytopenia, LLT: Immune thrombocytopenia - version MedDRA\\23.0. | Coder Import (b) (4) | 17 Mar 2021 02:11:35 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | (b) (4)              |                      |
| Data point term sent to Coder   | System               | 17 Mar 2021 02:10:16 |
| DataPoint Un-verified.  | (b) (4), (b) (6)     | 17 Mar 2021 02:09:52 |
| Signature has been broken.  | (b) (4), (b) (6)     | 17 Mar 2021 02:09:52 |
| User entered 'IMMUNE THROMBOCYTOPENIA' reason for change: Per Query Resolution  | (b) (4), (b) (6)     | 17 Mar 2021 02:09:52 |
| User opened query 'For coding purposes, please split ITP WITH SIGNIFICANT DROP OF THE   | Coder Import (b) (4) | 16 Mar 2021 18:32:53 |
| PLATELET COUNT into separate entries. 1. ITP (spell out abbreviation) and 2. SIGNIFICANT DROP OF THE PLATELET COUNT' (Site from System).  | (b) (4)              |                      |
| User signature succeeded.   | Bindu Balani (b) (4) | 13 Mar 2021 23:41:58 |
| DataPoint Verified.   | (b) (4)              |                      |
|   | (b) (4), (b) (6)     | 18 Feb 2021 18:33:06 |
| Data point term sent to Coder   | System               | 16 Feb 2021 15:20:16 |
| User entered 'ITP with significant drop of the platelet count'  | (b) (4), (b) (6)     | 16 Feb 2021 15:20:00 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:13:32**

[Was this a medically-attended AE?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:33:06 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)            | 16 Feb 2021 15:20:00 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:13:32**

[Was this a Solicited Adverse Reaction?](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:33:06 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                      | 18 Feb 2021 16:14:19 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                      | 18 Feb 2021 16:14:19 |
| User entered 'No (N)' reason for change: New Information                               | (b) (4), (b) (6)            | 18 Feb 2021 16:14:19 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                      | 16 Feb 2021 15:20:00 |
| User entered empty.  | (b) (4), (b) (6)            | 16 Feb 2021 15:20:00 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:13:32**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:33:06 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 16 Feb 2021 15:20:00 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:13:32**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                 | Time (GMT)           |
|----------------------------|----------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4) | 13 Mar 2021 23:41:58 |
| DataPoint Verified.        | (b) (4)              |                      |
|                            | (b) (4), (b) (6)     | 18 Feb 2021 18:33:06 |
| User entered '12 Feb 2021' | (b) (4), (b) (6)     | 16 Feb 2021 15:20:00 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:13:32**

[Start time \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:33:06 |
| User entered empty.       | (b) (4), (b) (6)            | 16 Feb 2021 15:20:00 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:13:32**

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 16 Feb 2021 15:20:00 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:13:32**

[Ongoing?](#)

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| User signature succeeded.   | Bindu Balani (b) (4) | 13 Mar 2021 23:41:58 |
| DataPoint Verified.   | (b) (4)              |                      |
|   | (b) (4), (b) (6)     | 23 Feb 2021 02:01:21 |
| User closed query 'Per progress note, this condition was resolved on 2/15/21. Update data.' (Site from CRA).              | (b) (4), (b) (6)     | 23 Feb 2021 02:01:16 |
| Query 'Per progress note, this condition was resolved on 2/15/21. Update data.' answered with 'Updated.' (Site from CRA). | (b) (4), (b) (6)     | 22 Feb 2021 20:40:13 |
| User entered 'No (N)' reason for change: New Information  | (b) (4), (b) (6)     | 22 Feb 2021 20:40:06 |
| User opened query 'Per progress note, this condition was resolved on 2/15/21. Update data.' (Site from CRA).              | (b) (4), (b) (6)     | 22 Feb 2021 20:18:08 |
| DataPoint Un-verified.  | (b) (4), (b) (6)     | 22 Feb 2021 20:17:31 |
| DataPoint Verified.   | (b) (4), (b) (6)     | 18 Feb 2021 18:33:06 |
| User entered 'Yes (Y)'  | (b) (4), (b) (6)     | 16 Feb 2021 15:20:00 |



**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:13:32**

*If not Ongoing, end date (dd MMM yyyy)*

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.                                     | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 02:01:19 |
| DataPoint Un-verified.  | (b) (4), (b) (6)            | 22 Feb 2021 20:40:06 |
| User entered '15 Feb 2021' reason for change: New Information | (b) (4), (b) (6)            | 22 Feb 2021 20:40:06 |
| DataPoint Verified.   | (b) (4), (b) (6)            | 18 Feb 2021 18:33:06 |
| User entered empty.   | (b) (4), (b) (6)            | 16 Feb 2021 15:20:00 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:13:32**

[End time \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:33:06 |
| User entered empty.       | (b) (4), (b) (6)            | 16 Feb 2021 15:20:00 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:13:32**

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 16 Feb 2021 15:20:00 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:13:32**

[Severity](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                      | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.                            | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:33:06 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | (b) (4), (b) (6)            | 16 Feb 2021 15:20:00 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:13:32**

[Is the adverse event serious?](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:33:06 |
| User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System). | System                      | 16 Feb 2021 15:20:57 |
| User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System). | System                      | 16 Feb 2021 15:20:00 |
| User entered 'Yes (Y)'   | (b) (4), (b) (6)            | 16 Feb 2021 15:20:00 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:13:32**

[Death](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4) | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 18 Feb 2021 18:33:06 |
| User entered '0'          | (b) (4), (b) (6)     | 16 Feb 2021 15:20:00 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:13:32**

[Life threatening](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4) | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 18 Feb 2021 18:33:06 |
| User entered '0'          | (b) (4), (b) (6)     | 16 Feb 2021 15:20:00 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:13:32**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4) | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 18 Feb 2021 18:33:06 |
| User entered '0'          | (b) (4), (b) (6)     | 16 Feb 2021 15:20:00 |



**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:13:32**

**Hospital Admission Date** (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:33:06 |
| User entered empty.       | (b) (4), (b) (6)            | 16 Feb 2021 15:20:00 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:13:32**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:33:06 |
| User entered empty.       | (b) (4), (b) (6)            | 16 Feb 2021 15:20:00 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:13:32**

[Admitted to ICU?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:33:06 |
| User entered empty.       | (b) (4), (b) (6)            | 16 Feb 2021 15:20:00 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:13:32**

[Number of Days in ICU](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:33:06 |
| User entered empty.       | (b) (4), (b) (6)            | 16 Feb 2021 15:20:00 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:13:32**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4) | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)              | 18 Feb 2021 18:33:06 |
| User entered '0'          | (b) (4), (b) (6)     | 16 Feb 2021 15:20:00 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:13:32**

[Congenital anomaly or birth defect](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4) | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 18 Feb 2021 18:33:06 |
| User entered '0'          | (b) (4), (b) (6)     | 16 Feb 2021 15:20:00 |

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**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:13:32**

[Other medically important event](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                            | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.                                  | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:33:06 |
| User entered '1' reason for change: Data Entry Error | (b) (4), (b) (6)            | 16 Feb 2021 15:20:57 |
| User entered '0'                                     | (b) (4), (b) (6)            | 16 Feb 2021 15:20:00 |

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:13:32

[Relationship to investigational product](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.   | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User closed query 'PV Query: Since the subject received both study drugs before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).                         | (b) (4), (b) (6)            | 01 Mar 2021 14:34:44 |
| Query 'PV Query: Since the subject received both study drugs before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' answered with 'Updated per source.' (Site from Safety). | (b) (4), (b) (6)            | 26 Feb 2021 18:32:54 |
| DataPoint Un-verified.  | (b) (4), (b) (6)            | 26 Feb 2021 18:32:44 |
| User entered 'Not Related (NOT RELATED)' reason for change: New Information   | (b) (4), (b) (6)            | 26 Feb 2021 18:32:44 |
| User opened query 'PV Query: Since the subject received both study drugs before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).                         | (b) (4), (b) (6)            | 25 Feb 2021 14:28:55 |
| DataPoint Verified.   | (b) (4), (b) (6)            | 18 Feb 2021 18:33:06 |
| User entered 'Not Applicable (NOT APPLICABLE)'  | (b) (4), (b) (6)            | 16 Feb 2021 15:20:00 |



**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:13:32**

[Relationship to Study Procedure](#)

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| User signature succeeded.                      | Bindu Balani (b) (4) | 13 Mar 2021 23:41:58 |
| DataPoint Verified.                            | (b) (4)              |                      |
|  | (b) (4), (b) (6)     | 11 Mar 2021 15:21:03 |
| DataPoint Un-verified.                         | (b) (4), (b) (6)     | 09 Mar 2021 18:15:29 |
| User entered 'Not Related (NOT RELATED)'       | (b) (4), (b) (6)     | 09 Mar 2021 18:15:29 |
| reason for change: New Information             |                      |                      |
| DataPoint Verified.                            | (b) (4), (b) (6)     | 18 Feb 2021 18:33:06 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4), (b) (6)     | 16 Feb 2021 15:20:00 |

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:13:32

Action taken with investigational product

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4) | 13 Mar 2021 23:41:58 |
| DataPoint Verified.  | (b) (4)              |                      |
|  | (b) (4), (b) (6)     | 11 Mar 2021 15:21:03 |
| User closed query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).   | (b) (4), (b) (6)     | 09 Mar 2021 14:20:44 |
| Query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' answered with 'Relationship to Study Procedure is "Not Applicable" according to provider per source.' (Site from Safety). | (b) (4), (b) (6)     | 08 Mar 2021 21:40:14 |
| User opened query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).   | (b) (4), (b) (6)     | 05 Mar 2021 12:17:43 |
| User closed query 'PV Query: As the last dose of mRNA-1273 was given on 09Feb2021, please update the action taken with mRNA-1273 from none to not applicable.' (Site from Safety).   | (b) (4), (b) (6)     | 01 Mar 2021 14:34:49 |
| Query 'PV Query: As the last dose of mRNA-1273 was given on 09Feb2021, please update the action taken with mRNA-1273 from none to not applicable.' answered with 'Updated per source.' (Site from Safety).   | (b) (4), (b) (6)     | 26 Feb 2021 18:33:03 |
| DataPoint Un-verified.   | (b) (4), (b) (6)     | 26 Feb 2021 18:32:44 |
| User entered 'Not Applicable (NOT APPLICABLE)' reason for change: New Information  | (b) (4), (b) (6)     | 26 Feb 2021 18:32:44 |
| User opened query 'PV Query: As the last dose of mRNA-1273 was given on 09Feb2021, please update the action taken with mRNA-1273 from none to not applicable.' (Site from Safety).   | (b) (4), (b) (6)     | 25 Feb 2021 14:29:07 |
| DataPoint Verified.  | (b) (4), (b) (6)     | 18 Feb 2021 18:33:06 |

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EAB) (1725)

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[Action taken with investigational product](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'None (NONE)' | (b) (4), (b) (6) | 16 Feb 2021 15:20:00 |
|                            |                  |                      |

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Generated On: 10 Jun 2021 09:13:32

None

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.   | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' (Site from DM).  | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 03:56:25 |
| Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' answered with "'NO MEDS GIVEN FOR THE ITP ACUTE ATTACK<br>I DISCUSSED WITH THE HEMATOLOGIST WHO FEELS THAT IT IS UNKNOWN IF THIS IS IMMUNE MEDIATED POST VACCINE VERSUS RELATED TO THE SHINGLES OUTBREAK THAT OCCURRED THE SAME TIME TEMPORALLY. SUBJECT PLATELETS WERE BACK UP TO 92K ON 2/15/21" per source. Please see narrative for more info. Thank you.' (Site from DM). | (b) (4), (b) (6)            | 08 Mar 2021 21:43:53 |
| User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' (Site from DM).  | (b) (4), (b) (6)            | 08 Mar 2021 06:43:49 |
| DataPoint Verified.   | (b) (4), (b) (6)            | 18 Feb 2021 18:33:06 |
| User entered 'I'  | (b) (4), (b) (6)            | 16 Feb 2021 15:20:00 |

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**Generated On: 10 Jun 2021 09:13:32**

[Concomitant Medication](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4) | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 18 Feb 2021 18:33:06 |
| User entered '0'          | (b) (4), (b) (6)     | 16 Feb 2021 15:20:00 |

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:13:32**

[Concomitant Procedure](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4) | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 18 Feb 2021 18:33:06 |
| User entered '0'          | (b) (4), (b) (6)     | 16 Feb 2021 15:20:00 |

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:13:32**

[Outcome](#)

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| User signature succeeded.   | Bindu Balani (b) (4) | 13 Mar 2021 23:41:58 |
| DataPoint Verified.   | (b) (4)              |                      |
|   | (b) (4), (b) (6)     | 11 Mar 2021 15:21:03 |
| DataPoint Un-verified.  | (b) (4), (b) (6)     | 22 Feb 2021 20:40:06 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: | (b) (4), (b) (6)     | 22 Feb 2021 20:40:06 |
| New Information   |                      |                      |
| DataPoint Verified.   | (b) (4), (b) (6)     | 18 Feb 2021 18:33:06 |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'    | (b) (4), (b) (6)     | 16 Feb 2021 15:20:00 |

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:33:06 |
| User entered empty.       | (b) (4), (b) (6)            | 16 Feb 2021 15:20:00 |



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Generated On: 10 Jun 2021 09:13:32

[Narrative](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User closed query 'Per DM CLR: Narrative = REPATED AGAIN TODAY ( 2/15 ). However, this is not recorded in the ConProc eCRF (i.e., Blood work-up). Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).                                | (b) (4), (b) (6) | 22 Mar 2021 15:33:11 |
| User closed query 'Per DM CLR: Narrative = REPEAT TESTS ON 2/12. However, this is not recorded in the ConProc eCRF (i.e., Blood work-up). Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).  | (b) (4), (b) (6) | 22 Mar 2021 15:33:09 |
| User closed query 'Per DM CLR: Narrative = SLIGHTLY LOWER PLATETET COUNT. However, this is not recorded in the ConProc eCRF (i.e., Blood work-up). Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).                               | (b) (4), (b) (6) | 22 Mar 2021 15:33:04 |
| Query 'Per DM CLR: Narrative = REPATED AGAIN TODAY ( 2/15 ). However, this is not recorded in the ConProc eCRF (i.e., Blood work-up). Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Updated in Con Procedure.' (Site from DM).  | (b) (4), (b) (6) | 19 Mar 2021 21:54:20 |
| Query 'Per DM CLR: Narrative = REPEAT TESTS ON 2/12. However, this is not recorded in the ConProc eCRF (i.e., Blood work-up). Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Updated in Con Procedure.' (Site from DM).          | (b) (4), (b) (6) | 19 Mar 2021 21:54:16 |
| Query 'Per DM CLR: Narrative = SLIGHTLY LOWER PLATETET COUNT. However, this is not recorded in the ConProc eCRF (i.e., Blood work-up). Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Updated in Con Procedure.' (Site from DM). | (b) (4), (b) (6) | 19 Mar 2021 21:54:13 |
| User opened query 'Per DM CLR: Narrative = REPATED AGAIN TODAY ( 2/15 ). However, this is not recorded in the ConProc eCRF (i.e., Blood work-up). Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).                                | (b) (4), (b) (6) | 18 Mar 2021 23:32:52 |

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[Narrative](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User opened query 'Per DM CLR: Narrative = REPEAT TESTS ON 2/12. However, this is not recorded in the ConProc eCRF (i.e., Blood work-up). Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).  | (b) (4), (b) (6)            | 18 Mar 2021 23:32:47 |
| User opened query 'Per DM CLR: Narrative = SLIGHTLY LOWER PLATETET COUNT. However, this is not recorded in the ConProc eCRF (i.e., Blood work-up). Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).   | (b) (4), (b) (6)            | 18 Mar 2021 23:32:41 |
| User signature succeeded.  | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User closed query 'Per DM CLR: Narrative indicates that subject had "KNOWN ITP HISTORY FOR YEARS." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).  | (b) (4), (b) (6)            | 10 Mar 2021 05:10:02 |
| User closed query 'PV Query: Please provide date of the latest platelets count prior to dose 1 of the vaccine and please provide the values?' (Site from Safety).  | (b) (4), (b) (6)            | 09 Mar 2021 14:23:09 |
| Query 'Per DM CLR: Narrative indicates that subject had "KNOWN ITP HISTORY FOR YEARS." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' answered with 'This information is recorded in Medical History tab. Please see entry/line #2 that reads "IMMUNE THROMOBCYTOPENIA - 1999", eCRF is in fact updated. Thank you.' (Site from DM). | (b) (4), (b) (6)            | 08 Mar 2021 21:49:40 |
| Query 'PV Query: Please provide date of the latest platelets count prior to dose 1 of the vaccine and please provide the values?' answered with 'No other information available as subject has a known history (for years) of ITP and routinely sees a hematologist for this.' (Site from Safety).   | (b) (4), (b) (6)            | 08 Mar 2021 21:45:09 |

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| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| User opened query 'Per DM CLR: Narrative indicates that subject had "KNOWN ITP HISTORY FOR YEARS." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF.' (Site from DM).  | (b) (4), (b) (6) | 08 Mar 2021 06:44:08 |
| User opened query 'PV Query: Please provide date of the latest platelets count prior to dose 1 of the vaccine and please provide the values?' (Site from Safety).   | (b) (4), (b) (6) | 05 Mar 2021 12:16:49 |
| User closed query 'PV Query: ITP history and chronicity after splenectomy: -what are the last several months platelet values, any drops, how often and what apparent causes for the drops, any treatment given chronically or at time of the platelets drops?' (Site from Safety).  | (b) (4), (b) (6) | 01 Mar 2021 14:35:02 |
| User closed query 'PV Query: Please provide dates of the blood sampling that show the recent drop in platelets and subsequent recovery.' (Site from Safety).  | (b) (4), (b) (6) | 01 Mar 2021 14:34:58 |
| User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).  | (b) (4), (b) (6) | 01 Mar 2021 14:34:53 |
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Data request for relevant laboratory and diagnostic test results (including units and reference ranges with patient identifiers and subject ID) will be sent by (b) (6) (b) (6).' (Site from Safety). | (b) (4), (b) (6) | 26 Feb 2021 18:30:20 |

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[Narrative](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Query 'PV Query: ITP history and chronicity after splenectomy: -what are the last several months platelet values, any drops, how often and what apparent causes for the drops, any treatment given chronically or at time of the platelets drops?' answered with 'All relevant information was scanned into source in the "Media" section and was sent to Moderna Safety via fax and email to Safety_Moderna@iqvia.com and fax to 866.599.1342' (Site from Safety). | (b) (4), (b) (6) | 26 Feb 2021 18:28:12 |
| Query 'PV Query: Please provide dates of the blood sampling that show the recent drop in platelets and subsequent recovery.' answered with 'All dates of blood sampling was scanned into source and was sent to Moderna Safety via fax and email to Safety_Moderna@iqvia.com and fax to 866.599.1342' (Site from Safety).   | (b) (4), (b) (6) | 26 Feb 2021 18:27:43 |
| User closed query 'PV Query: Please provide date of when the subject had platelet result of 92k.' (Site from Safety).   | (b) (4), (b) (6) | 26 Feb 2021 15:52:18 |
| User closed query 'PV Query: Please provide additional information on the shingles: start date, extent, treatment.' (Site from Safety).   | (b) (4), (b) (6) | 26 Feb 2021 15:52:12 |
| User closed query 'PV Query: Please provide date of the latest platelets count prior to dose 1 of the vaccine and please provide the values?' (Site from Safety).   | (b) (4), (b) (6) | 26 Feb 2021 15:52:08 |

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| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Query 'PV Query: Please provide date of the latest platelets count prior to dose 1 of the vaccine and please provide the values?' answered with 'Subject reports that she visited her hematologist for a final follow up appointment on 2/15/21. It was assessed at this visit that her platelets were back up to 92K. Subject reports that her hematologist felt comfortable with the upward trend and deemed no further follow ups were necessary. No medications were ordered at follow up appointment with hemologist on 2/15/21. Subject has been managing ITP diagnosis for many years and is highly attuned to her body and can recognize associated symptoms of disease process. She expressed that she felt completely back to normal by her 2/15/21 appointment with hemoatologist and voiced intention to continue to carefully self monitor. SAE Resolved as of 2/15/21.' (Site from Safety). | (b) (4), (b) (6) | 25 Feb 2021 21:56:27 |
| Query 'PV Query: Please provide additional information on the shingles: start date, extent, treatment.' answered with 'Subject clarifies that she has no prior medical history of Shingles (Already made into an A.E per Medidata).   | (b) (4), (b) (6) | 25 Feb 2021 21:53:48 |
| Start date: 1/10/21. End date: 11/Feb/2021.<br>Treatment: Valtrex (Valacyclovir Hydrochloride (documented in Con Meds already)  |                  |                      |
| For more details, please see A.E folder and Con Meds folder. Thank you.' (Site from Safety).<br>DataPoint Un-verified.  | (b) (4), (b) (6) | 25 Feb 2021 21:53:43 |

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[Narrative](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered 'PT WITH KNOWN ITP HISTORY FOR YEARS AND WENT FOR ROUTINE HEMATOLOGY VISIT ON FEB 9TH AND WAS NOTED TO HAVE SLIGHTLY LOWER PLATETET COUNT AND ALSO SHINGLES IN THE BUTTOCK AND WAS PRESCRIBED VALTREX . SHE THEN RECEIVED A SECOND DOSE OF THE MRNA 1273 AT 2PM ON 2/9/ 20 AND ON REPEAT TESTS ON 2/12 SHE HAD A VERY SIGNIFICANT DROP IN THE PLATELETS TO 28K AND THIS WAS REPATED AGAIN TODAY ( 2/15 ) AND WITH SOME IMPROVEMENT TO 68 K . SHE WILL BE AGAIN SEEN BY THE HEMATOLOGIST NEXT WEEK FOR THE SAME . <br /> <br />NO MEDS GIVEN FOR THE ITP ACUTE ATTACK <br />I DISCUSSED WITH THE HEMATOLOGIST WHO FEELS THAT IT IS UNKNOWN IF THIS IS IMMUNE MEDIATED POST VACCINE VERSUS RELATED TO THE SHINGLES OUTBREAK THAT OCCURRED THE SAME TIME TEMPORALLY. SUBJECT PLATELETS WERE BACK UP TO 92K on 2/15/21' reason for change:<br>New Information | (b) (4), (b) (6) | 25 Feb 2021 21:53:43 |
| Query 'PV Query: Please provide date of when the subject had platelet result of 92k.' answered with 'Date of when subject had platelet results of 92 k was on 2/15/21' (Site from Safety).   | (b) (4), (b) (6) | 25 Feb 2021 21:49:55 |
| User opened query 'PV Query: Please provide date of when the subject had platelet result of 92k.' (Site from Safety).  | (b) (4), (b) (6) | 25 Feb 2021 14:32:08 |
| User opened query 'PV Query: Please provide additional information on the shingles: start date, extent, treatment.' (Site from Safety).  | (b) (4), (b) (6) | 25 Feb 2021 14:32:01 |
| User opened query 'PV Query: ITP history and chronicity after splenectomy: -what are the last several months platelet values, any drops, how often and what apparent causes for the drops, any treatment given chronically or at time of the platelets drops?' (Site from Safety).   | (b) (4), (b) (6) | 25 Feb 2021 14:31:53 |

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| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User opened query 'PV Query: Please provide date of the latest platelets count prior to dose 1 of the vaccine and please provide the values?' (Site from Safety).  | (b) (4), (b) (6) | 25 Feb 2021 14:29:40 |
| User opened query 'PV Query: Please provide dates of the blood sampling that show the recent drop in platelets and subsequent recovery.' (Site from Safety).   | (b) (4), (b) (6) | 25 Feb 2021 14:29:27 |
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety). | (b) (4), (b) (6) | 25 Feb 2021 14:29:17 |
| DataPoint Verified.  | (b) (4), (b) (6) | 23 Feb 2021 02:01:34 |
| User closed query 'Per progress note, subject platelets were back up to 92K. Please update this narrative based on progress note.' (Site from CRA).  | (b) (4), (b) (6) | 23 Feb 2021 02:01:31 |
| Query 'Per progress note, subject platelets were back up to 92K. Please update this narrative based on progress note.' answered with 'Narrative updated.' (Site from CRA).   | (b) (4), (b) (6) | 22 Feb 2021 20:40:26 |
| DataPoint Un-verified.   | (b) (4), (b) (6) | 22 Feb 2021 20:40:06 |

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| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| User entered 'PT WITH KNOWN ITP HISTORY FOR YEARS AND WENT FOR ROUTINE HEMATOLOGY VISIT ON FEB 9TH AND WAS NOTED TO HAVE SLIGHTLY LOWER PLATETET COUNT AND ALSO SHINGLES IN THE BUTTOCK AND WAS PRESCRIBED VALTREX . SHE THEN RECEIVED A SECOND DOSE OF THE MRNA 1273 AT 2PM ON 2/9/ 20 AND ON REPEAT TESTS ON 2/12 SHE HAD A VERY SIGNIFICANT DROP IN THE PLATELETS TO 28K AND THIS WAS REPATED AGAIN TODAY ( 2/15 ) AND WITH SOME IMPROVEMENT TO 68 K . SHE WILL BE AGAIN SEEN BY THE HEMATOLOGIST NEXT WEEK FOR THE SAME . <br /> <br />NO MEDS GIVEN FOR THE ITP ACUTE ATTACK <br />I DISCUSSED WITH THE HEMATOLOGIST WHO FEELS THAT IT IS UNKNOWN IF THIS IS IMMUNE MEDIATED POST VACCINE VERSUS RELATED TO THE SHINGLES OUTBREAK THAT OCCURRED THE SAME TIME TEMPORALLY. Subject platelets were back up to 92K.' reason for change: New Information | (b) (4), (b) (6) | 22 Feb 2021 20:40:06 |
| User opened query 'Per progress note, subject platelets were back up to 92K. Please update this narrative based on progress note.' (Site from CRA). DataPoint Verified.   | (b) (4), (b) (6) | 22 Feb 2021 20:22:19 |
|   | (b) (4), (b) (6) | 18 Feb 2021 18:33:06 |



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[Narrative](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| User entered 'Pt with known ITP history for years and went for Routine hematology visit on Feb 9th and was noted to have slightly lower platelet count and also shingles in the buttock and was prescribed Valtrex . She then received a second dose of the mRNA 1273 at 2pm on 2/9/ 20 and on repeat tests on 2/12 she had a very significant drop in the platelets to 28k and this was repeated again today ( 2/15 ) and with some improvement to 68 k . She will be again seen by the hematologist next week for the same . <br /> <br />No meds given for the ITP acute attack <br />I discussed with the hematologist who feels that it is unknown if this is immune mediated post vaccine versus related to the Shingles outbreak that occurred the same time temporally' | (b) (4), (b) (6) | 16 Feb 2021 15:20:00 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:13:32**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 16 Feb 2021 15:20:00 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:13:32**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 16 Feb 2021 15:20:00 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:32**

[AEID](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:32:18 |

US3602123

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:13:32

[Adverse event](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                | 28 Apr 2021 20:32:18 |
| User signature succeeded.   | Bindu Balani (b) (4)            | 13 Mar 2021 23:41:58 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)     | 11 Mar 2021 15:21:03 |
| User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes zoster, LLT: Shingles - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4) | 22 Feb 2021 23:39:49 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.   | Coder Import (b) (4)<br>(b) (4) | 22 Feb 2021 23:39:49 |
| Data point term sent to Coder   | System                          | 22 Feb 2021 20:57:41 |
| User entered 'PRESUMPTIVE SHINGLES'   | (b) (4), (b) (6)                | 22 Feb 2021 20:57:24 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:32**

[Was this a medically-attended AE?](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 28 Apr 2021 20:32:18 |
| User signature succeeded.                                  | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4), (b) (6)            | 24 Feb 2021 15:41:15 |
| User entered 'No (N)'                                      | (b) (4), (b) (6)            | 22 Feb 2021 20:57:24 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:32**

[Was this a Solicited Adverse Reaction?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:18 |
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 22 Feb 2021 20:57:24 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:32**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:18 |
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 22 Feb 2021 20:57:24 |



**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:32**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 20:32:18 |
| User signature succeeded.  | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered '10 Jan 2021' | (b) (4), (b) (6)            | 22 Feb 2021 20:57:24 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:32**

[Start time \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:18 |
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered empty.       | (b) (4), (b) (6)            | 22 Feb 2021 20:57:24 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:32**

[AE start date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 20:32:18 |
| User entered empty. | System           | 22 Feb 2021 20:57:24 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:32**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:18 |
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 22 Feb 2021 20:57:24 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:32**

*If not Ongoing, end date (dd MMM yyyy)*

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 20:32:18 |
| User signature succeeded.  | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered '11 Feb 2021' | (b) (4), (b) (6)            | 22 Feb 2021 20:57:24 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:32**

**End time (00:00-23:59)**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:18 |
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered empty.       | (b) (4), (b) (6)            | 22 Feb 2021 20:57:24 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:32**

[AE End Date and Time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 20:32:18 |
| User entered empty. | System           | 22 Feb 2021 20:57:24 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:32**

[Severity](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 28 Apr 2021 20:32:18 |
| User signature succeeded.                  | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.                        | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | (b) (4), (b) (6)            | 22 Feb 2021 20:57:24 |



**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:32**

[Is the adverse event serious?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:18 |
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 22 Feb 2021 20:57:24 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:32**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:18 |
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered '0'          | (b) (4), (b) (6)            | 22 Feb 2021 20:57:24 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:32**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:18 |
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered '0'          | (b) (4), (b) (6)            | 22 Feb 2021 20:57:24 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:32**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:18 |
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered '0'          | (b) (4), (b) (6)            | 22 Feb 2021 20:57:24 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:32**

**Hospital Admission Date (dd MMM yyyy)**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:18 |
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered empty.       | (b) (4), (b) (6)            | 22 Feb 2021 20:57:24 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:32**

**Hospital Discharge Date (dd MMM yyyy)**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:18 |
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered empty.       | (b) (4), (b) (6)            | 22 Feb 2021 20:57:24 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:32**

[Admitted to ICU?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:18 |
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered empty.       | (b) (4), (b) (6)            | 22 Feb 2021 20:57:24 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:32**

[Number of Days in ICU](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:18 |
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered empty.       | (b) (4), (b) (6)            | 22 Feb 2021 20:57:24 |



**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:32**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:18 |
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered '0'          | (b) (4), (b) (6)            | 22 Feb 2021 20:57:24 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:32**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:18 |
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered '0'          | (b) (4), (b) (6)            | 22 Feb 2021 20:57:24 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:32**

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:18 |
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered '0'          | (b) (4), (b) (6)            | 22 Feb 2021 20:57:24 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:32**

[Relationship to investigational product](#)

| Audit                                    | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)            | 28 Apr 2021 20:32:18 |
| User signature succeeded.                | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.                      | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6)            | 22 Feb 2021 20:57:24 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:32**

[Relationship to Study Procedure](#)

| Audit                                    | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)            | 28 Apr 2021 20:32:18 |
| User signature succeeded.                | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.                      | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6)            | 22 Feb 2021 20:57:24 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:32**

[Action taken with investigational product](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 20:32:18 |
| User signature succeeded.  | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered 'None (NONE)' | (b) (4), (b) (6)            | 22 Feb 2021 20:57:24 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:32**

[None](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:18 |
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered '0'          | (b) (4), (b) (6)            | 22 Feb 2021 20:57:24 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:32**

[Concomitant Medication](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:18 |
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered 'l'          | (b) (4), (b) (6)            | 22 Feb 2021 20:57:24 |



**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:32**

[Concomitant Procedure](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:18 |
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered '0'          | (b) (4), (b) (6)            | 22 Feb 2021 20:57:24 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:32**

[Outcome](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 28 Apr 2021 20:32:18 |
| User signature succeeded.                                 | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.                                       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered 'Recovered/Resolved<br>(RECOVERED/RESOLVED)' | (b) (4), (b) (6)            | 22 Feb 2021 20:57:24 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:32**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:18 |
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered empty.       | (b) (4), (b) (6)            | 22 Feb 2021 20:57:24 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:32**

[Narrative](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:18 |
| User signature succeeded. | Bindu Balani (b) (4)        | 13 Mar 2021 23:41:58 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:21:03 |
| User entered empty.       | (b) (4), (b) (6)            | 22 Feb 2021 20:57:24 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:32**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:32:18 |
| User entered '0'  | System           | 22 Feb 2021 20:57:24 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:32**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:32:18 |
| User entered '1'  | System           | 24 Feb 2021 15:41:15 |
| User entered '0'  | System           | 22 Feb 2021 20:57:24 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:13:32**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 20:32:18 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:13:32**

[AEID](#)

| Audit                                 | User                 | Time (GMT)           |
|---------------------------------------|----------------------|----------------------|
| User signature succeeded.             | Bindu Balani (b) (4) | 05 Apr 2021 21:29:37 |
| User entered                          | (b) (4)              |                      |
| 'USA-US079-2021-mRNA-1273-P301000002' | (b) (4), (b) (6)     | 17 Mar 2021 19:50:40 |



US3602123

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:13:32

[Adverse event](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| User signature succeeded.   | Bindu Balani (b) (4)            | 05 Apr 2021 21:29:37 |
| User coded data point as SOC: Investigations, HLGT: Haematology investigations (incl blood groups), HLT: Platelet analyses, PT: Platelet count decreased, LLT: Platelet count decreased - version MedDRA\\23.0. | (b) (4)<br>Coder Import (b) (4) | 19 Mar 2021 14:13:33 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.   | Coder Import (b) (4)            | 19 Mar 2021 14:13:33 |
| Data point term sent to Coder   | System                          | 17 Mar 2021 02:15:18 |
| User entered 'SIGNIFICANT DROP OF THE PLATELET COUNT'   | (b) (4), (b) (6)                | 17 Mar 2021 02:15:03 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:13:32**

[Was this a medically-attended AE?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 17 Mar 2021 02:15:03 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:13:32**

[Was this a Solicited Adverse Reaction?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 17 Mar 2021 02:15:03 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:13:32**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 17 Mar 2021 02:15:03 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:13:32**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered '12 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 17 Mar 2021 02:15:03 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:13:32**

[Start time \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 17 Mar 2021 02:15:03 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:13:32**

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 17 Mar 2021 02:15:03 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:13:32**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 17 Mar 2021 02:15:03 |



**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:13:32**

*If not Ongoing, end date (dd MMM yyyy)*

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered '15 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 17 Mar 2021 02:15:03 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:13:32**

**End time (00:00-23:59)**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 17 Mar 2021 02:15:03 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:13:32**

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 17 Mar 2021 02:15:03 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:13:32**

[Severity](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                      | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | (b) (4)<br>(b) (4), (b) (6) | 17 Mar 2021 02:15:03 |

US3602123

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:13:32

[Is the adverse event serious?](#)

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4) | 05 Apr 2021 21:29:37 |
| User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System). | (b) (4)<br>System    | 17 Mar 2021 02:16:13 |
| User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System). | System               | 17 Mar 2021 02:15:03 |
| User entered 'Yes (Y)'   | (b) (4), (b) (6)     | 17 Mar 2021 02:15:03 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:13:32**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 17 Mar 2021 02:15:03 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:13:32**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 17 Mar 2021 02:15:03 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:13:32**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 17 Mar 2021 02:15:03 |



**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:13:32**

**Hospital Admission Date** (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 17 Mar 2021 02:15:03 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:13:32**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 17 Mar 2021 02:15:03 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:13:32**

[Admitted to ICU?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 17 Mar 2021 02:15:03 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:13:32**

[Number of Days in ICU](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 17 Mar 2021 02:15:03 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:13:32**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 17 Mar 2021 02:15:03 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:13:32**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 17 Mar 2021 02:15:03 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:13:32**

[Other medically important event](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                            | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered '1' reason for change: Data Entry Error | (b) (4)<br>(b) (4), (b) (6) | 17 Mar 2021 02:16:13 |
| User entered '0'                                     | (b) (4), (b) (6)            | 17 Mar 2021 02:15:03 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:13:32**

[Relationship to investigational product](#)

| Audit                                    | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered 'Not Related (NOT RELATED)' | (b) (4)<br>(b) (4), (b) (6) | 17 Mar 2021 02:15:03 |



**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:13:32**

[Relationship to Study Procedure](#)

| Audit                                    | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered 'Not Related (NOT RELATED)' | (b) (4)<br>(b) (4), (b) (6) | 17 Mar 2021 02:15:03 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:13:32**

[Action taken with investigational product](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                      | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4)<br>(b) (4), (b) (6) | 17 Mar 2021 02:15:03 |

US3602123

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:13:32

None

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded for this condition which is unexpected. Please review and ensure that CM/ConProc for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given.<br>' (Site from DM).  | (b) (4), (b) (6) | 07 Apr 2021 04:19:19 |
| Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded for this condition which is unexpected. Please review and ensure that CM/ConProc for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given.<br>' answered with 'Per source "PT WITH KNOWN ITP HISTORY FOR YEARS AND WENT FOR ROUTINE HEMATOLOGY VISIT ON FEB 9TH AND WAS NOTED TO HAVE SLIGHTLY LOWER PLATETET COUNT. SUBJECT WAS THEN RECEIVED A SECOND DOSE OF THE MRNA 1273 AT 2PM ON 2/9/ 20. SUBJECT HAD A VERY SIGNIFICANT DROP IN THE PLATELETS TO 28K AND THIS WAS REPATED AGAIN TODAY ( 2/15 ) AND WITH SOME IMPROVEMENT TO 68 K . SHE WILL BE AGAIN SEEN BY THE HEMATOLOGIST NEXT WEEK FOR THE SAME .<br><br>NO MEDS GIVEN FOR THE ITP ACUTE ATTACK<br>DISCUSSED WITH THE HEMATOLOGIST WHO FEELS THAT IT IS UNKNOWN IF THIS IS IMMUNE MEDIATED POST VACCINE VERSUS RELATED TO THE SHINGLES OUTBREAK THAT OCCURRED THE SAME TIME TEMPORALLY. SUBJECT PLATELETS WERE BACK UP TO 92K ON 2/15/21' (Site from DM). | (b) (4), (b) (6) | 06 Apr 2021 15:42:40 |

US3602123

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:13:32

None

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| User opened query 'Per DM CLR: Serious= YES.<br>However, there is no CM/ConProc recorded for this<br>condition which is unexpected. Please review and<br>ensure that CM/ConProc for this serious condition is<br>added in the appropriate eCRFs. Update as<br>applicable. Otherwise, provide comment for no<br>treatment given. <br />' (Site from DM).<br>User signature succeeded. | (b) (4), (b) (6)     | 06 Apr 2021 07:57:37 |
|  | Bindu Balani (b) (4) | 05 Apr 2021 21:29:37 |
| User entered 'I'   | (b) (4), (b) (6)     | 17 Mar 2021 02:15:03 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:13:32**

[Concomitant Medication](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 17 Mar 2021 02:15:03 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:13:32**

[Concomitant Procedure](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 17 Mar 2021 02:15:03 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:13:32**

[Outcome](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                              | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4)<br>(b) (4), (b) (6) | 17 Mar 2021 02:15:03 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:13:32**

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 17 Mar 2021 02:15:03 |



US3602123

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:13:32

[Narrative](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.   | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered 'PT WITH KNOWN ITP HISTORY FOR YEARS AND WENT FOR ROUTINE HEMATOLOGY VISIT ON FEB 9TH AND WAS NOTED TO HAVE SLIGHTLY LOWER PLATETET COUNT AND ALSO SHINGLES IN THE BUTTOCK AND WAS PRESCRIBED VALTREX . SHE THEN RECEIVED A SECOND DOSE OF THE MRNA 1273 AT 2PM ON 2/9/ 20 AND ON REPEAT TESTS ON 2/12 SHE HAD A VERY SIGNIFICANT DROP IN THE PLATELETS TO 28K AND THIS WAS REPATED AGAIN TODAY ( 2/15 ) AND WITH SOME IMPROVEMENT TO 68 K . SHE WILL BE AGAIN SEEN BY THE HEMATOLOGIST NEXT WEEK FOR THE SAME . | (b) (4)<br>(b) (4), (b) (6) | 17 Mar 2021 02:15:03 |
| NO MEDS GIVEN FOR THE ITP ACUTE ATTACK<br>I DISCUSSED WITH THE HEMATOLOGIST WHO FEELS THAT IT IS UNKNOWN IF THIS IS IMMUNE MEDIATED POST VACCINE VERSUS RELATED TO THE SHINGLES OUTBREAK THAT OCCURRED THE SAME TIME TEMPORALLY. SUBJECT PLATELETS WERE BACK UP TO 92K ON 2/15/21'  |                             |                      |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:13:32**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 17 Mar 2021 02:15:03 |

**US3602123**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:13:32**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 17 Mar 2021 02:15:03 |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:13:32

Were any prior/concomitant medications and/or vaccinations taken?

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 03 May 2021 08:46:18 |
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User closed query 'Per CDM: Response noted. Kindly reconcile and update the corresponding conmed page for day 7 (08OCT2020) and Day 8 (09OCT2020). Thank you.' (Site from DM).   | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 08:12:18 |
| Query 'Per CDM: Response noted. Kindly reconcile and update the corresponding conmed page for day 7 (08OCT2020) and Day 8 (09OCT2020). Thank you.' answered with 'Updated ' (Site from DM).  | (b) (4), (b) (6)            | 20 Nov 2020 18:41:36 |
| User opened query 'Per CDM: Response noted. Kindly reconcile and update the corresponding conmed page for day 7 (08OCT2020) and Day 8 (09OCT2020). Thank you.' (Site from DM).   | (b) (4), (b) (6)            | 19 Nov 2020 10:18:16 |
| User closed query 'Per CDM re-query: Response noted. However, Conmed "Tylenol" recorded with start and stop date as "05-OCT-2020" which is not corresponding with Day 5 (06 OCT 2020) on Diary dose 1. Also please reconcile Conmed dates for Diary Dose 1 Day 7 (08OCT2020), Day 8 (09OCT2020). Thank you.' (Site from DM).             | (b) (4), (b) (6)            | 19 Nov 2020 10:18:16 |
| Query 'Per CDM re-query: Response noted. However, Conmed "Tylenol" recorded with start and stop date as "05-OCT-2020" which is not corresponding with Day 5 (06 OCT 2020) on Diary dose 1. Also please reconcile Conmed dates for Diary Dose 1 Day 7 (08OCT2020), Day 8 (09OCT2020). Thank you.' answered with 'Updated' (Site from DM). | (b) (4), (b) (6)            | 18 Nov 2020 00:44:15 |
| User opened query 'Per CDM re-query: Response noted. However, Conmed "Tylenol" recorded with start and stop date as "05-OCT-2020" which is not corresponding with Day 5 (06 OCT 2020) on Diary dose 1. Also please reconcile Conmed dates for Diary Dose 1 Day 7 (08OCT2020), Day 8 (09OCT2020). Thank you.' (Site from DM).             | (b) (4), (b) (6)            | 06 Nov 2020 05:51:36 |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:13:32

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User closed query 'Per CDM re-query: Response noted. However, kindly provide the Concomitant Log line # to confirm the medication taken for Day 5 (06 OCT 2020) on Diary dose 1, and if it is not entered then please consider to record it appropriately on Prior/Concomitant medications page. Thank you.' (Site from DM).   | (b) (4), (b) (6) | 06 Nov 2020 05:51:36 |
| Query 'Per CDM re-query: Response noted. However, kindly provide the Concomitant Log line # to confirm the medication taken for Day 5 (06 OCT 2020) on Diary dose 1, and if it is not entered then please consider to record it appropriately on Prior/Concomitant medications page. Thank you.' answered with 'Already reported in con meds, medication was taken for "HEADACHE DURING DAY 5 REPORTED ON SAFETY CALL DAY 8 - A.E" Medication was Tylenol .' (Site from DM). | (b) (4), (b) (6) | 05 Nov 2020 18:02:49 |
| User opened query 'Per CDM re-query: Response noted. However, kindly provide the Concomitant Log line # to confirm the medication taken for Day 5 (06 OCT 2020) on Diary dose 1, and if it is not entered then please consider to record it appropriately on Prior/Concomitant medications page. Thank you.' (Site from DM).   | (b) (4), (b) (6) | 28 Oct 2020 08:56:06 |
| User closed query 'Per CDM: Per the participant response, medication was taken to treat pain or fever for Day 5 (06 OCT 2020) on Diary dose 1, however, please confirm the participant medication details and record the medication on the concomitant medication pages. Thank you.' (Site from DM).   | (b) (4), (b) (6) | 28 Oct 2020 08:56:06 |
| Query 'Per CDM: Per the participant response, medication was taken to treat pain or fever for Day 5 (06 OCT 2020) on Diary dose 1, however, please confirm the participant medication details and record the medication on the concomitant medication pages. Thank you.' answered with 'Info acquired and inserted' (Site from DM).  | (b) (4), (b) (6) | 27 Oct 2020 15:35:51 |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:13:32

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User opened query 'Per CDM: Per the participant response, medication was taken to treat pain or fever for Day 5 (06 OCT 2020) on Diary dose 1, however, please confirm the participant medication details and record the medication on the concomitant medication pages. Thank you.' (Site from DM). | (b) (4), (b) (6) | 12 Oct 2020 05:14:04 |
| User entered 'Yes (Y)'   | (b) (4), (b) (6) | 02 Oct 2020 20:53:12 |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:13:32

Name of Medication

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| User signature succeeded.   | Bindu Balani (b) (4)            | 05 Apr 2021 21:29:37 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)     | 11 Mar 2021 15:29:50 |
| User closed query 'Per progress notes for SAE, subject had shingles on the buttocks and was prescribed Valtrex. Verify if Valrex should be added to the ConlMed page and update data accordingly.' (Site from CRA).   | (b) (4), (b) (6)                | 11 Mar 2021 15:20:11 |
| DataPoint Un-verified.  | (b) (4), (b) (6)                | 11 Mar 2021 15:20:05 |
| DataPoint Verified.   | (b) (4), (b) (6)                | 11 Mar 2021 15:19:04 |
| Query 'Per progress notes for SAE, subject had shingles on the buttocks and was prescribed Valtrex. Verify if Valrex should be added to the ConlMed page and update data accordingly.' answered with 'Updated.' (Site from CRA).  | (b) (4), (b) (6)                | 22 Feb 2021 20:43:41 |
| User opened query 'Per progress notes for SAE, subject had shingles on the buttocks and was prescribed Valtrex. Verify if Valrex should be added to the ConlMed page and update data accordingly.' (Site from CRA).   | (b) (4), (b) (6)                | 18 Feb 2021 19:13:48 |
| User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;FERROUS FUMARATE;NORETHISTERONE ACETATE, PRODUCTSYNONYM: MINASTRIN 24 FE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 14 Oct 2020 11:44:32 |
| 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 Oct 2020 11:44:32 |
| Data point term sent to Coder   | System                          | 02 Oct 2020 20:55:15 |
| User entered 'Minastrin 28 day cycle'   | (b) (4), (b) (6)                | 02 Oct 2020 20:54:26 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Prophylaxis](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 11 Mar 2021 15:29:50 |
| DataPoint Un-verified.    | (b) (4), (b) (6)     | 11 Mar 2021 15:20:02 |
| DataPoint Verified.       | (b) (4), (b) (6)     | 11 Mar 2021 15:19:14 |
| User entered 'No (N)'     | (b) (4), (b) (6)     | 02 Oct 2020 20:54:26 |



**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Indication](#)

| Audit                            | User                        | Time (GMT)           |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded.        | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.              | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'For contraception' | (b) (4), (b) (6)            | 02 Oct 2020 20:54:26 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'I'          | (b) (4), (b) (6)            | 02 Oct 2020 20:54:26 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Dose unit](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'tablet (TABLET)' | (b) (4), (b) (6)            | 02 Oct 2020 20:54:26 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:32**

[If dose unit is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 02 Oct 2020 20:54:26 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'once daily (QD)' | (b) (4), (b) (6)            | 02 Oct 2020 20:54:26 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:32**

[If frequency is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 02 Oct 2020 20:54:26 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)            | 02 Oct 2020 20:54:26 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:32**

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 02 Oct 2020 20:54:26 |



**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'un UNK 2017' | (b) (4), (b) (6)            | 02 Oct 2020 20:54:26 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered '0'          | (b) (4), (b) (6)            | 02 Oct 2020 20:54:26 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)            | 02 Oct 2020 20:54:26 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:32**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 02 Oct 2020 20:54:26 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 02 Oct 2020 20:54:26 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 02 Oct 2020 20:54:26 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 02 Oct 2020 20:54:26 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 02 Oct 2020 20:54:26 |



US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:13:32

[Name of Medication](#)

| Audit   | User                            | Time (GMT)                                   |
|---|---------------------------------|--|
| User signature succeeded.   | Bindu Balani (b) (4)            | 05 Apr 2021 21:29:37                         |
| DataPoint Verified.   | (b) (4)                         |  |
|   | (b) (4), (b) (6)                | 11 Mar 2021 15:29:50                         |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: CALCIUM<br>CHANNEL BLOCKERS, ATC: SELECTIVE<br>CALCIUM CHANNEL BLOCKERS WITH<br>MAINLY VASCULAR EFFECTS, ATC:<br>DIHYDROPYRIDINE DERIVATIVES, PRODUCT:<br>AMLODIPINE - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 02 Oct 2020 20:56:53                         |
| 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) | 02 Oct 2020 20:56:53                         |
| Data point term sent to Coder<br>User entered 'Amlodipine'  | System<br>(b) (4), (b) (6)      | 02 Oct 2020 20:55:15<br>02 Oct 2020 20:55:14 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 02 Oct 2020 20:55:14 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Indication](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'for HTN'    | (b) (4), (b) (6)            | 02 Oct 2020 20:55:14 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered '10'         | (b) (4), (b) (6)            | 02 Oct 2020 20:55:14 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'mg (mg)'    | (b) (4), (b) (6)            | 02 Oct 2020 20:55:14 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:32**

[If dose unit is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 02 Oct 2020 20:55:14 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'once daily (QD)' | (b) (4), (b) (6)            | 02 Oct 2020 20:55:14 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:32**

[If frequency is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 02 Oct 2020 20:55:14 |



**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)            | 02 Oct 2020 20:55:14 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:32**

[If route of administration is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 02 Oct 2020 20:55:14 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'un UNK 2018' | (b) (4), (b) (6)            | 02 Oct 2020 20:55:14 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered '0'          | (b) (4), (b) (6)            | 02 Oct 2020 20:55:14 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)            | 02 Oct 2020 20:55:14 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:32**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 02 Oct 2020 20:55:14 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 02 Oct 2020 20:55:14 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 02 Oct 2020 20:55:14 |



**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 02 Oct 2020 20:55:14 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 02 Oct 2020 20:55:14 |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:32

[Name of Medication](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| User signature succeeded.   | Bindu Balani (b) (4)            | 05 Apr 2021 21:29:37 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)     | 11 Mar 2021 15:29:50 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: CENTRALLY ACTING ANTI OBESITY PRODUCTS, PRODUCT: PHENTERMINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 19 Dec 2020 00:08:46 |
| 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) | 19 Dec 2020 00:08:46 |
| Data point term sent to Coder   | System                          | 01 Dec 2020 16:14:46 |
| Coding entries removed.   | (b) (4), (b) (6)                | 01 Dec 2020 16:13:52 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: CENTRALLY ACTING ANTI OBESITY PRODUCTS, PRODUCT: PHENTERMINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 03 Oct 2020 05:15:39 |
| 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) | 03 Oct 2020 05:15:39 |
| Data point term sent to Coder   | System                          | 02 Oct 2020 20:57:19 |
| User entered 'Phentermine'  | (b) (4), (b) (6)                | 02 Oct 2020 20:56:33 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:32**

[Prophylaxis](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.                                 | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.                                       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'Yes (Y)' reason for change: New Information | (b) (4), (b) (6)            | 01 Dec 2020 16:13:52 |
| User entered 'No (N)'                                     | (b) (4), (b) (6)            | 02 Oct 2020 20:56:33 |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:13:32

[Indication](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (not the drug class or action of drug). Please reconcile with AE or Med History eCRF so there is an appropriate condition recorded.<br>' (Site from DM). | (b) (4), (b) (6)            | 02 Dec 2020 14:37:47 |
| Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (not the drug class or action of drug). Please reconcile with AE or Med History eCRF so there is an appropriate condition recorded.                                  | (b) (4), (b) (6)            | 01 Dec 2020 16:13:59 |
| ' answered with 'Updated per EMR' (Site from DM).  |                             |                      |
| User entered 'Dietary supplement to prevent weight gain' reason for change: New Information  | (b) (4), (b) (6)            | 01 Dec 2020 16:13:52 |
| User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (not the drug class or action of drug). Please reconcile with AE or Med History eCRF so there is an appropriate condition recorded.<br>' (Site from DM). | (b) (4), (b) (6)            | 24 Nov 2020 12:27:12 |
| User entered 'for weight loss x 4 months'  | (b) (4), (b) (6)            | 02 Oct 2020 20:56:33 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:32**

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered '30'         | (b) (4), (b) (6)            | 02 Oct 2020 20:56:33 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:32**

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'mg (mg)'    | (b) (4), (b) (6)            | 02 Oct 2020 20:56:33 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:32**

[If dose unit is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 02 Oct 2020 20:56:33 |



**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:32**

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'once daily (QD)' | (b) (4), (b) (6)            | 02 Oct 2020 20:56:33 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:32**

[If frequency is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 02 Oct 2020 20:56:33 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:32**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)            | 02 Oct 2020 20:56:33 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:32**

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 02 Oct 2020 20:56:33 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:32**

[Start date \(dd MMM yyyy\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 02 Oct 2020 20:56:33 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:32**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'I'          | (b) (4), (b) (6)            | 02 Oct 2020 20:56:33 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:32**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 02 Oct 2020 20:56:33 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:32**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered '28 Sep 2020' | (b) (4), (b) (6)            | 02 Oct 2020 20:56:33 |



**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:32**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 02 Oct 2020 20:56:33 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:32**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 02 Oct 2020 20:56:33 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:32**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 02 Oct 2020 20:56:33 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:13:32**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 02 Oct 2020 20:56:33 |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:32

Name of Medication

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4) | 05 Apr 2021 21:29:37 |
| DataPoint Verified.  | (b) (4)              |                      |
|  | (b) (4), (b) (6)     | 11 Mar 2021 15:29:50 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.                               | Coder Import (b) (4) | 08 Oct 2020 23:19:55 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4) | 08 Oct 2020 23:19:55 |
| Data point term sent to Coder  | System               | 06 Oct 2020 16:21:51 |
| User closed query 'CDM-Coding: The trade name can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' (Site from System).  | System               | 06 Oct 2020 16:20:56 |
| Query 'CDM-Coding: The trade name can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' answered with 'Final diagnosis inserted per EMR/EHR' (Site from System). | (b) (4), (b) (6)     | 06 Oct 2020 16:20:56 |
| User opened query 'CDM-Coding: The trade name can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' (Site from System).  | Coder Import (b) (4) | 03 Oct 2020 04:13:47 |
| Data point term sent to Coder  | System               | 02 Oct 2020 20:58:22 |
| User entered 'Zyrtec'  | (b) (4), (b) (6)     | 02 Oct 2020 20:57:26 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:32**

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 02 Oct 2020 20:57:26 |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:13:32

[Indication](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.   | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User closed query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication within this timeframe. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.' | (b) (4), (b) (6)            | 02 Dec 2020 14:39:10 |
| (Site from DM).   |                             |                      |
| Query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication within this timeframe. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.'             | (b) (4), (b) (6)            | 01 Dec 2020 16:10:26 |
| ' answered with 'Updated' (Site from DM).   |                             |                      |
| User opened query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication within this timeframe. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.' | (b) (4), (b) (6)            | 24 Nov 2020 12:24:08 |
| (Site from DM).   |                             |                      |
| User entered 'for seasonal allergies'   | (b) (4), (b) (6)            | 02 Oct 2020 20:57:26 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:32**

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered '10'         | (b) (4), (b) (6)            | 02 Oct 2020 20:57:26 |



**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:32**

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'mg (mg)'    | (b) (4), (b) (6)            | 02 Oct 2020 20:57:26 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:32**

[If dose unit is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 02 Oct 2020 20:57:26 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:32**

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'once daily (QD)' | (b) (4), (b) (6)            | 02 Oct 2020 20:57:26 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:32**

[If frequency is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 02 Oct 2020 20:57:26 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:32**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)            | 02 Oct 2020 20:57:26 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:32**

[If route of administration is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 02 Oct 2020 20:57:26 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:32**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'un UNK 2018' | (b) (4), (b) (6)            | 02 Oct 2020 20:57:26 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:32**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered '0'          | (b) (4), (b) (6)            | 02 Oct 2020 20:57:26 |



**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:32**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)            | 02 Oct 2020 20:57:26 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:32**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 02 Oct 2020 20:57:26 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:32**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 02 Oct 2020 20:57:26 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:32**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 02 Oct 2020 20:57:26 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:32**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 02 Oct 2020 20:57:26 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:13:32**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 02 Oct 2020 20:57:26 |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:32

[Name of Medication](#)

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| User signature succeeded.   | Bindu Balani (b) (4) | 05 Apr 2021 21:29:37 |
| DataPoint Verified.   | (b) (4)              |                      |
|   | (b) (4), (b) (6)     | 11 Mar 2021 15:29:50 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 03 Oct 2020 04:18:51 |
|   | (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 Oct 2020 04:18:51 |
|   | (b) (4)              |                      |
| Data point term sent to Coder   | System               | 02 Oct 2020 20:59:25 |
| User entered 'Vitamin C'  | (b) (4), (b) (6)     | 02 Oct 2020 20:58:32 |
|   |                      |                      |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:32

[Prophylaxis](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User closed query 'Per CDM: Prophylaxis is No, however; indication recorded may indicate medication was given as a prophylaxis. Please review and update as appropriate or else clarify. Thank you.' (Site from DM).             | (b) (4), (b) (6)            | 19 Nov 2020 04:20:34 |
| Query 'Per CDM: Prophylaxis is No, however; indication recorded may indicate medication was given as a prophylaxis. Please review and update as appropriate or else clarify. Thank you.' answered with 'Updated' (Site from DM). | (b) (4), (b) (6)            | 18 Nov 2020 00:36:02 |
| User entered 'Yes (Y)' reason for change: Data Entry Error   | (b) (4), (b) (6)            | 18 Nov 2020 00:35:57 |
| User opened query 'Per CDM: Prophylaxis is No, however; indication recorded may indicate medication was given as a prophylaxis. Please review and update as appropriate or else clarify. Thank you.' (Site from DM).             | (b) (4), (b) (6)            | 05 Nov 2020 12:07:59 |
| User entered 'No (N)'  | (b) (4), (b) (6)            | 02 Oct 2020 20:58:32 |



**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:13:32**

[Indication](#)

| Audit                         | User                        | Time (GMT)           |
|-------------------------------|-----------------------------|----------------------|
| User signature succeeded.     | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.           | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'for supplement' | (b) (4), (b) (6)            | 02 Oct 2020 20:58:32 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:13:32**

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered '1000'       | (b) (4), (b) (6)            | 02 Oct 2020 20:58:32 |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:32

[Dose unit](#)

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| User signature succeeded.   | Bindu Balani (b) (4) | 05 Apr 2021 21:29:37 |
| DataPoint Verified.   | (b) (4)              |                      |
|   | (b) (4), (b) (6)     | 11 Mar 2021 15:29:50 |
| User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).   | (b) (4), (b) (6)     | 29 Jan 2021 11:42:50 |
| Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'Re-confirmed dosing unit. Per source IU was recorded.' (Site from DM). | (b) (4), (b) (6)     | 28 Jan 2021 15:52:50 |
| User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).   | (b) (4), (b) (6)     | 28 Jan 2021 03:53:32 |
| User entered 'IU (IU)' reason for change: New Information   | (b) (4), (b) (6)     | 01 Dec 2020 16:14:27 |
| User entered 'Other (OTHER)'  | (b) (4), (b) (6)     | 02 Oct 2020 20:58:32 |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:13:32

If dose unit is Other, specify

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.   | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User closed query 'Per CDM: "Dose unit - Other" is recorded as "U" as there is an available option in the listed choices for "Dose unit", please review and select an appropriate option from the drop-down list provided in the CRF and update accordingly else clarify.' (Site from DM).                    | (b) (4), (b) (6)            | 02 Dec 2020 14:08:35 |
| Query 'Per CDM: "Dose unit - Other" is recorded as "U" as there is an available option in the listed choice for "Dose unit", please review and select an appropriate option from the drop-down list provided in the CRF and update accordingly else clarify.' answered with 'Updated per EMR' (Site from DM). | (b) (4), (b) (6)            | 01 Dec 2020 16:14:35 |
| User entered empty; reason for change New Information   | (b) (4), (b) (6)            | 01 Dec 2020 16:14:27 |
| User opened query 'Per CDM: "Dose unit - Other" is recorded as "U" as there is an available option in the listed choices for "Dose unit", please review and select an appropriate option from the drop-down list provided in the CRF and update accordingly else clarify.' (Site from DM).                    | (b) (4), (b) (6)            | 25 Nov 2020 09:55:29 |
| User entered 'u'  | (b) (4), (b) (6)            | 02 Oct 2020 20:58:32 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:13:32**

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'once daily (QD)' | (b) (4), (b) (6)            | 02 Oct 2020 20:58:32 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:13:32**

[If frequency is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 02 Oct 2020 20:58:32 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:13:32**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)            | 02 Oct 2020 20:58:32 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:13:32**

[If route of administration is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 02 Oct 2020 20:58:32 |



**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:13:32**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'un UNK 2019' | (b) (4), (b) (6)            | 02 Oct 2020 20:58:32 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:13:32**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered '0'          | (b) (4), (b) (6)            | 02 Oct 2020 20:58:32 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:13:32**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)            | 02 Oct 2020 20:58:32 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:13:32**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 02 Oct 2020 20:58:32 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:13:32**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 02 Oct 2020 20:58:32 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:13:32**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 02 Oct 2020 20:58:32 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:13:32**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 02 Oct 2020 20:58:32 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:13:32**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 02 Oct 2020 20:58:32 |



US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:13:32

[Name of Medication](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)            | 05 Apr 2021 21:29:37 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)     | 11 Mar 2021 15:29:50 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 03 Oct 2020 06:57:41 |
| 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) | 03 Oct 2020 06:57:41 |
| Data point term sent to Coder  | System                          | 02 Oct 2020 21:00:25 |
| User entered 'Magnesium'   | (b) (4), (b) (6)                | 02 Oct 2020 20:59:27 |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:13:32

[Prophylaxis](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User closed query 'Per CDM: Prophylaxis is No, however; indication recorded may indicate medication was given as a prophylaxis. Please review and update as appropriate or else clarify. Thank you.' (Site from DM).             | (b) (4), (b) (6)            | 19 Nov 2020 04:20:46 |
| Query 'Per CDM: Prophylaxis is No, however; indication recorded may indicate medication was given as a prophylaxis. Please review and update as appropriate or else clarify. Thank you.' answered with 'Updated' (Site from DM). | (b) (4), (b) (6)            | 18 Nov 2020 00:36:20 |
| User entered 'Yes (Y)' reason for change: Data Entry Error   | (b) (4), (b) (6)            | 18 Nov 2020 00:36:15 |
| User opened query 'Per CDM: Prophylaxis is No, however; indication recorded may indicate medication was given as a prophylaxis. Please review and update as appropriate or else clarify. Thank you.' (Site from DM).             | (b) (4), (b) (6)            | 05 Nov 2020 12:08:55 |
| User entered 'No (N)'  | (b) (4), (b) (6)            | 02 Oct 2020 20:59:27 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:32**

[Indication](#)

| Audit                         | User                        | Time (GMT)           |
|-------------------------------|-----------------------------|----------------------|
| User signature succeeded.     | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.           | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'for supplement' | (b) (4), (b) (6)            | 02 Oct 2020 20:59:27 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:32**

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered '450'        | (b) (4), (b) (6)            | 02 Oct 2020 20:59:27 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:32**

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'mg (mg)'    | (b) (4), (b) (6)            | 02 Oct 2020 20:59:27 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:32**

[If dose unit is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 02 Oct 2020 20:59:27 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:32**

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'once daily (QD)' | (b) (4), (b) (6)            | 02 Oct 2020 20:59:27 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:32**

[If frequency is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 02 Oct 2020 20:59:27 |



**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:32**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)            | 02 Oct 2020 20:59:27 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:32**

[If route of administration is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 02 Oct 2020 20:59:27 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:32**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'un UNK 2019' | (b) (4), (b) (6)            | 02 Oct 2020 20:59:27 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:32**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered '0'          | (b) (4), (b) (6)            | 02 Oct 2020 20:59:27 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:32**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)            | 02 Oct 2020 20:59:27 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:32**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 02 Oct 2020 20:59:27 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:32**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 02 Oct 2020 20:59:27 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:32**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 02 Oct 2020 20:59:27 |



**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:32**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 02 Oct 2020 20:59:27 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:13:32**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 02 Oct 2020 20:59:27 |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:32

Name of Medication

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)            | 05 Apr 2021 21:29:37 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)     | 11 Mar 2021 15:29:50 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 03 Oct 2020 05:14:53 |
| 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) | 03 Oct 2020 05:14:53 |
| Data point term sent to Coder  | System                          | 02 Oct 2020 21:00:26 |
| User entered 'Potassium'   | (b) (4), (b) (6)                | 02 Oct 2020 21:00:14 |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:13:32

[Prophylaxis](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User closed query 'Per CDM: Prophylaxis is No, however; indication recorded may indicate medication was given as a prophylaxis. Please review and update as appropriate or else clarify. Thank you.' (Site from DM).             | (b) (4), (b) (6)            | 19 Nov 2020 04:21:00 |
| Query 'Per CDM: Prophylaxis is No, however; indication recorded may indicate medication was given as a prophylaxis. Please review and update as appropriate or else clarify. Thank you.' answered with 'Updated' (Site from DM). | (b) (4), (b) (6)            | 18 Nov 2020 00:36:35 |
| User entered 'Yes (Y)' reason for change: Data Entry Error   | (b) (4), (b) (6)            | 18 Nov 2020 00:36:29 |
| User opened query 'Per CDM: Prophylaxis is No, however; indication recorded may indicate medication was given as a prophylaxis. Please review and update as appropriate or else clarify. Thank you.' (Site from DM).             | (b) (4), (b) (6)            | 05 Nov 2020 12:09:38 |
| User entered 'No (N)'  | (b) (4), (b) (6)            | 02 Oct 2020 21:00:14 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:32**

[Indication](#)

| Audit                         | User                        | Time (GMT)           |
|-------------------------------|-----------------------------|----------------------|
| User signature succeeded.     | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.           | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'for supplement' | (b) (4), (b) (6)            | 02 Oct 2020 21:00:14 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:32**

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered '200'        | (b) (4), (b) (6)            | 02 Oct 2020 21:00:14 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:32**

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'mg (mg)'    | (b) (4), (b) (6)            | 02 Oct 2020 21:00:14 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:32**

[If dose unit is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 02 Oct 2020 21:00:14 |



**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:32**

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'once daily (QD)' | (b) (4), (b) (6)            | 02 Oct 2020 21:00:14 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:32**

[If frequency is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 02 Oct 2020 21:00:14 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:32**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)            | 02 Oct 2020 21:00:14 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:32**

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 02 Oct 2020 21:00:14 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:32**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'un UNK 2019' | (b) (4), (b) (6)            | 02 Oct 2020 21:00:14 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:32**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered '0'          | (b) (4), (b) (6)            | 02 Oct 2020 21:00:14 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:32**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)            | 02 Oct 2020 21:00:14 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:32**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 02 Oct 2020 21:00:14 |



**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:32**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 02 Oct 2020 21:00:14 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:32**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 02 Oct 2020 21:00:14 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:32**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 02 Oct 2020 21:00:14 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:13:32**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 02 Oct 2020 21:00:14 |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:32

[Name of Medication](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)            | 05 Apr 2021 21:29:37 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)     | 11 Mar 2021 15:29:50 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 05 Nov 2020 18:02:20 |
| 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) | 05 Nov 2020 18:02:20 |
| Data point term sent to Coder  | System                          | 05 Nov 2020 18:01:32 |
| Coding entries removed.  | (b) (4), (b) (6)                | 05 Nov 2020 18:01:21 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 27 Oct 2020 15:20:37 |
| 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) | 27 Oct 2020 15:20:37 |
| Data point term sent to Coder  | System                          | 27 Oct 2020 15:19:05 |
| User entered 'Tylenol'   | (b) (4), (b) (6)                | 27 Oct 2020 15:18:19 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:13:32**

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 27 Oct 2020 15:18:19 |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:32

[Indication](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'HEADACHE DURING Day 5<br>REPORTED ON SAFETY CALL DAY 8 - A.E'<br>reason for change: Data Entry Error | (b) (4), (b) (6)            | 05 Nov 2020 18:01:21 |
| User entered 'Headache during Safety Call Day 8 -<br>A.E'  | (b) (4), (b) (6)            | 27 Oct 2020 15:18:19 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:13:32**

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered '1000'       | (b) (4), (b) (6)            | 27 Oct 2020 15:18:19 |



**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:13:32**

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'mg (mg)'    | (b) (4), (b) (6)            | 27 Oct 2020 15:18:19 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:13:32**

[If dose unit is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 27 Oct 2020 15:18:19 |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:13:32

[Frequency](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.   | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| 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).             | System                      | 18 Nov 2020 00:43:36 |
| 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                      | 18 Nov 2020 00:43:36 |
| User entered 'once daily (QD)' reason for change: Data Entry Error  | (b) (4), (b) (6)            | 18 Nov 2020 00:43:36 |
| 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).             | System                      | 18 Nov 2020 00:43:11 |
| User entered 'once (ONCE)' reason for change: Data Entry Error  | (b) (4), (b) (6)            | 18 Nov 2020 00:40:45 |
| User entered 'once daily (QD)'  | (b) (4), (b) (6)            | 27 Oct 2020 15:18:19 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:13:32**

[If frequency is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 27 Oct 2020 15:18:19 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:13:32**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)            | 27 Oct 2020 15:18:19 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:13:32**

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 27 Oct 2020 15:18:19 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:13:32**

[Start date \(dd MMM yyyy\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered '5 Oct 2020' | (b) (4), (b) (6)            | 27 Oct 2020 15:18:19 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:13:32**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered '0'          | (b) (4), (b) (6)            | 27 Oct 2020 15:18:19 |



**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:13:32**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 27 Oct 2020 15:18:19 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:13:32**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| User signature succeeded.                                     | Bindu Balani (b) (4) | 05 Apr 2021 21:29:37 |
| DataPoint Verified.   | (b) (4)              |                      |
|   | (b) (4), (b) (6)     | 11 Mar 2021 15:29:50 |
| User entered '6 Oct 2020' reason for change: Data Entry Error | (b) (4), (b) (6)     | 18 Nov 2020 00:43:11 |
| User entered '5 Oct 2020'                                     | (b) (4), (b) (6)     | 27 Oct 2020 15:18:19 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:13:32**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)            | 27 Oct 2020 15:18:19 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:13:32**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1'    | System | 18 Nov 2020 00:43:36 |
| User entered empty. | System | 18 Nov 2020 00:40:45 |
| User entered '1'    | System | 27 Oct 2020 15:18:19 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:13:32**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1'    | System | 18 Nov 2020 00:43:36 |
| User entered empty. | System | 18 Nov 2020 00:40:45 |
| User entered '1'    | System | 27 Oct 2020 15:18:19 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:13:32**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 18 Nov 2020 00:43:36 |
| User entered empty.      | System | 18 Nov 2020 00:40:45 |
| User entered '804 (804)' | System | 27 Oct 2020 15:18:19 |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:32

Name of Medication

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)            | 05 Apr 2021 21:29:37 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)     | 11 Mar 2021 15:29:50 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM CARBONATE, PRODUCTSYNONYM: TUMS [CALCIUM CARBONATE] - version WHODrug-Global-B3\\202003.                         | Coder Import (b) (4)<br>(b) (4) | 22 Nov 2020 05:58:34 |
| 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) | 22 Nov 2020 05:58:34 |
| Data point term sent to Coder  | System                          | 18 Nov 2020 00:38:11 |
| Coding entries removed.  | (b) (4), (b) (6)                | 18 Nov 2020 00:37:33 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: ANTACIDS, ATC: CALCIUM COMPOUNDS, PRODUCT: CALCIUM CARBONATE, PRODUCTSYNONYM: TUMS [CALCIUM CARBONATE] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 01 Nov 2020 16:54:18 |
| 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) | 01 Nov 2020 16:54:18 |
| Data point term sent to Coder  | System                          | 27 Oct 2020 15:29:17 |
| User entered 'TUMS'  | (b) (4), (b) (6)                | 27 Oct 2020 15:28:50 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:13:32**

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 27 Oct 2020 15:28:50 |



US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:32

[Indication](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.   | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'A.E: QUEASY STOMACH - reported in Safety Day #8' reason for change: New Information | (b) (4), (b) (6)            | 18 Nov 2020 00:38:06 |
| User entered 'QUEASY STOMACH' reason for change: Data Entry Error                                 | (b) (4), (b) (6)            | 18 Nov 2020 00:37:33 |
| User entered 'queasy stomach and heart burn'  | (b) (4), (b) (6)            | 27 Oct 2020 15:28:50 |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:32

[Dose per administration](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 500 MG, 1000 MCG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.<br>' (Site from DM).   | (b) (4), (b) (6)            | 29 Jan 2021 11:43:06 |
| Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 500 MG, 1000 MCG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.<br>' answered with 'Subject does not recall. Only "2 tablets" were recorded in source. Thank you.' (Site from DM). | (b) (4), (b) (6)            | 28 Jan 2021 15:55:38 |
| User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 500 MG, 1000 MCG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.<br>' (Site from DM).   | (b) (4), (b) (6)            | 28 Jan 2021 03:54:26 |
| User entered '2'   | (b) (4), (b) (6)            | 27 Oct 2020 15:28:50 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:13:32**

[Dose unit](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'tablet (TABLET)' | (b) (4), (b) (6)            | 27 Oct 2020 15:28:50 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:13:32**

[If dose unit is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 27 Oct 2020 15:28:50 |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:13:32

[Frequency](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User closed query 'Per DM CLR: Frequency = Once, however the Con Med is still ongoing. Please update the frequency on the CM eCRF page or provide an explanation.<br>' (Site from DM). | (b) (4), (b) (6)            | 23 Dec 2020 13:58:58 |
| Query 'Per DM CLR: Frequency = Once, however the Con Med is still ongoing. Please update the frequency on the CM eCRF page or provide an explanation.                                  | (b) (4), (b) (6)            | 22 Dec 2020 15:55:44 |
| ' answered with 'Updated' (Site from DM).  |                             |                      |
| User entered 'once daily (QD)' reason for change: Data Entry Error   | (b) (4), (b) (6)            | 22 Dec 2020 15:55:38 |
| User opened query 'Per DM CLR: Frequency = Once, however the Con Med is still ongoing. Please update the frequency on the CM eCRF page or provide an explanation.<br>' (Site from DM). | (b) (4), (b) (6)            | 22 Dec 2020 05:31:38 |
| User entered 'once (ONCE)' reason for change: Data Entry Error   | (b) (4), (b) (6)            | 18 Nov 2020 00:37:33 |
| User entered 'once daily (QD)'   | (b) (4), (b) (6)            | 27 Oct 2020 15:28:50 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:13:32**

[If frequency is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 27 Oct 2020 15:28:50 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:13:32**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)            | 27 Oct 2020 15:28:50 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:13:32**

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 27 Oct 2020 15:28:50 |



**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:13:32**

[Start date \(dd MMM yyyy\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered '7 Oct 2020' | (b) (4), (b) (6)            | 27 Oct 2020 15:28:50 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:13:32**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered '0'          | (b) (4), (b) (6)            | 27 Oct 2020 15:28:50 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:13:32**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)            | 27 Oct 2020 15:28:50 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:13:32**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 27 Oct 2020 15:28:50 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:13:32**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 27 Oct 2020 15:28:50 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:13:32**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1'    | System | 22 Dec 2020 15:55:38 |
| User entered empty. | System | 18 Nov 2020 00:37:33 |
| User entered '1'    | System | 27 Oct 2020 15:28:50 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:13:32**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1'    | System | 22 Dec 2020 15:55:38 |
| User entered empty. | System | 18 Nov 2020 00:37:33 |
| User entered '1'    | System | 27 Oct 2020 15:28:50 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:13:32**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 22 Dec 2020 15:55:38 |
| User entered empty.      | System | 18 Nov 2020 00:37:33 |
| User entered '804 (804)' | System | 27 Oct 2020 15:28:50 |



US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:13:32

[Name of Medication](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)            | 05 Apr 2021 21:29:37 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)     | 11 Mar 2021 15:29:50 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: ANTACIDS, ATC: CALCIUM COMPOUNDS, PRODUCT: CALCIUM CARBONATE, PRODUCTSYNONYM: TUMS [CALCIUM CARBONATE] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 22 Nov 2020 05:58:34 |
| 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) | 22 Nov 2020 05:58:34 |
| Data point term sent to Coder  | System                          | 18 Nov 2020 00:39:11 |
| User entered 'TUMS'  | (b) (4), (b) (6)                | 18 Nov 2020 00:38:59 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:13:32**

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 18 Nov 2020 00:38:59 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:13:32**

[Indication](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'A.E: Heart Burn - reported in Safety Day #8' | (b) (4), (b) (6)            | 18 Nov 2020 00:38:59 |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:13:32

[Dose per administration](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 500 MG, 1000 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.<br>' (Site from DM).  | (b) (4), (b) (6)            | 29 Jan 2021 11:43:11 |
| Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 500 MG, 1000 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.<br>' answered with 'Subject does not recall. Only "2 tablet" were recorded in source. Thank you.' (Site from DM). | (b) (4), (b) (6)            | 28 Jan 2021 15:56:58 |
| User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 500 MG, 1000 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.<br>' (Site from DM).  | (b) (4), (b) (6)            | 28 Jan 2021 03:55:16 |
| User entered '2'   | (b) (4), (b) (6)            | 18 Nov 2020 00:38:59 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:13:32**

[Dose unit](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'tablet (TABLET)' | (b) (4), (b) (6)            | 18 Nov 2020 00:38:59 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:13:32**

[If dose unit is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 18 Nov 2020 00:38:59 |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:13:32

[Frequency](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User closed query 'Per DM CLR: Frequency = Once, however the Con Med is still ongoing. Please update the frequency on the CM eCRF page or provide an explanation.<br>' (Site from DM). | (b) (4), (b) (6)            | 23 Dec 2020 13:59:07 |
| Query 'Per DM CLR: Frequency = Once, however the Con Med is still ongoing. Please update the frequency on the CM eCRF page or provide an explanation.                                  | (b) (4), (b) (6)            | 22 Dec 2020 15:56:28 |
| ' answered with 'Updated' (Site from DM).  |                             |                      |
| User entered 'once daily (QD)' reason for change: Data Entry Error   | (b) (4), (b) (6)            | 22 Dec 2020 15:56:22 |
| User opened query 'Per DM CLR: Frequency = Once, however the Con Med is still ongoing. Please update the frequency on the CM eCRF page or provide an explanation.<br>' (Site from DM). | (b) (4), (b) (6)            | 22 Dec 2020 05:32:27 |
| User entered 'once (ONCE)'   | (b) (4), (b) (6)            | 18 Nov 2020 00:38:59 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:13:32**

[If frequency is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 18 Nov 2020 00:38:59 |



**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:13:32**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)            | 18 Nov 2020 00:38:59 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:13:32**

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 18 Nov 2020 00:38:59 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:13:32**

[Start date \(dd MMM yyyy\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered '7 Oct 2020' | (b) (4), (b) (6)            | 18 Nov 2020 00:38:59 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:13:32**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered '0'          | (b) (4), (b) (6)            | 18 Nov 2020 00:38:59 |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:13:32

[Ongoing?](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                      | 18 Nov 2020 00:39:18 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                      | 18 Nov 2020 00:39:18 |
| User entered 'Yes (Y)' reason for change: Data Entry Error                             | (b) (4), (b) (6)            | 18 Nov 2020 00:39:18 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                      | 18 Nov 2020 00:38:59 |
| User entered empty.  | (b) (4), (b) (6)            | 18 Nov 2020 00:38:59 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:13:32**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 18 Nov 2020 00:38:59 |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:13:32

[Was this medication taken for solicited event?](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                      | 18 Nov 2020 00:39:18 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                      | 18 Nov 2020 00:39:18 |
| User entered 'No (N)' reason for change: Data Entry Error                              | (b) (4), (b) (6)            | 18 Nov 2020 00:39:18 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                      | 18 Nov 2020 00:38:59 |
| User entered empty.  | (b) (4), (b) (6)            | 18 Nov 2020 00:38:59 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:13:32**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered '1'    | System | 22 Dec 2020 15:56:22 |
| User entered empty. | System | 18 Nov 2020 00:38:59 |



**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:13:32**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'I'    | System | 22 Dec 2020 15:56:22 |
| User entered empty. | System | 18 Nov 2020 00:38:59 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:13:32**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 22 Dec 2020 15:56:22 |
| User entered empty.      | System | 18 Nov 2020 00:38:59 |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:13:32

[Name of Medication](#)

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| User signature succeeded.   | Bindu Balani (b) (4) | 05 Apr 2021 21:29:37 |
| DataPoint Verified.   | (b) (4)              |                      |
|   | (b) (4), (b) (6)     | 11 Mar 2021 15:29:50 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL EXTRA STRENGTH - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 07 Dec 2020 17:59:14 |
|   | (b) (4)              |                      |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4) | 07 Dec 2020 17:59:14 |
|   | (b) (4)              |                      |
| Data point term sent to Coder   | System               | 07 Dec 2020 17:36:19 |
| User entered 'Tylenol Extra Strength'   | (b) (4), (b) (6)     | 07 Dec 2020 17:35:28 |
|   |                      |                      |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:32**

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 07 Dec 2020 17:35:28 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:32**

[Indication](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'Headache - reported for Diary Dose 1 on Day 5 on 10/6 via e-Diary' | (b) (4), (b) (6)            | 07 Dec 2020 17:35:28 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:32**

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered '1000'       | (b) (4), (b) (6)            | 07 Dec 2020 17:35:28 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:32**

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'mg (mg)'    | (b) (4), (b) (6)            | 07 Dec 2020 17:35:28 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:32**

[If dose unit is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 07 Dec 2020 17:35:28 |



**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:32**

[Frequency](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'once (ONCE)' | (b) (4), (b) (6)            | 07 Dec 2020 17:35:28 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:32**

[If frequency is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 07 Dec 2020 17:35:28 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:32**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)            | 07 Dec 2020 17:35:28 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:32**

[If route of administration is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 07 Dec 2020 17:35:28 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:32**

[Start date \(dd MMM yyyy\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered '6 Oct 2020' | (b) (4), (b) (6)            | 07 Dec 2020 17:35:28 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:32**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered '0'          | (b) (4), (b) (6)            | 07 Dec 2020 17:35:28 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:32**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 07 Dec 2020 17:35:28 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:32**

**If not Ongoing, End date (*dd MMM yyyy*)**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered '6 Oct 2020' | (b) (4), (b) (6)            | 07 Dec 2020 17:35:28 |



**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:32**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)            | 07 Dec 2020 17:35:28 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:32**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 07 Dec 2020 17:35:28 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:32**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 07 Dec 2020 17:35:28 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:13:32**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 07 Dec 2020 17:35:28 |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:13:32

[Name of Medication](#)

| Audit  | User                            | Time (GMT)                                   |
|--|---------------------------------|--|
| User signature succeeded.  | Bindu Balani (b) (4)            | 05 Apr 2021 21:29:37                         |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)     | 11 Mar 2021 15:29:50                         |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 16 Feb 2021 15:55:58                         |
| 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) | 16 Feb 2021 15:55:58                         |
| Data point term sent to Coder Coding entries removed.  | System<br>(b) (4), (b) (6)      | 16 Feb 2021 15:39:54<br>16 Feb 2021 15:39:14 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 16 Feb 2021 15:36:59                         |
| 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) | 16 Feb 2021 15:36:59                         |
| Data point term sent to Coder User entered 'Tylenol'   | System<br>(b) (4), (b) (6)      | 16 Feb 2021 15:35:42<br>16 Feb 2021 15:35:15 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:13:32**

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 16 Feb 2021 15:35:15 |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:13:32

[Indication](#)

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| User signature succeeded.   | Bindu Balani (b) (4) | 05 Apr 2021 21:29:37 |
| DataPoint Verified.   | (b) (4)              |                      |
|   | (b) (4), (b) (6)     | 11 Mar 2021 15:29:50 |
| User closed query 'Per DM CLR: Note, there is no any corresponding data on Diary or AE that matches this Con Med indication during indicated timeframe. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' (Site from DM).   | (b) (4), (b) (6)     | 11 Mar 2021 03:50:24 |
| Query 'Per DM CLR: Note, there is no any corresponding data on Diary or AE that matches this Con Med indication during indicated timeframe. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' answered with 'Data was taken from source, documentation states that a visit follow-up phone call was made which occurred on February 9th, 2021- the same day the EUA vaccine # 2 was given to the subject. Medication "Tylenol" was taken to treat symptoms that the subject experienced after the injection. This information should have been captured in e-Diary. Thank you.' (Site from DM). | (b) (4), (b) (6)     | 10 Mar 2021 03:23:36 |
| User opened query 'Per DM CLR: Note, there is no any corresponding data on Diary or AE that matches this Con Med indication during indicated timeframe. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' (Site from DM).   | (b) (4), (b) (6)     | 09 Mar 2021 04:54:43 |
| User entered 'FEVER 100.7, HEADACHE, Redness to left arm - injection site, Swelling to left arm - injection site, Pain to left arm - injection site, Tenderness to left arm - injection site, Bruise to left arm' reason for change: Data Entry Error   | (b) (4), (b) (6)     | 16 Feb 2021 15:39:14 |
| User entered 'FEVER 100.7 and Headache' reason for change: Data Entry Error   | (b) (4), (b) (6)     | 16 Feb 2021 15:35:34 |
| User entered 'Fever 100.7'  | (b) (4), (b) (6)     | 16 Feb 2021 15:35:15 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:13:32**

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered '500'        | (b) (4), (b) (6)            | 16 Feb 2021 15:35:15 |



**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:13:32**

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'mg (mg)'    | (b) (4), (b) (6)            | 16 Feb 2021 15:35:15 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:13:32**

If dose unit is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 16 Feb 2021 15:35:15 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:13:32**

[Frequency](#)

| Audit                        | User                        | Time (GMT)           |
|------------------------------|-----------------------------|----------------------|
| User signature succeeded.    | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.          | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'other (OTHER)' | (b) (4), (b) (6)            | 16 Feb 2021 15:35:15 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:13:32**

[If frequency is Other, specify](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'x q12 x 5 doses' | (b) (4), (b) (6)            | 16 Feb 2021 15:35:15 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:13:32**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)            | 16 Feb 2021 15:35:15 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:13:32**

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 16 Feb 2021 15:35:15 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:13:32**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered '10 Feb 2021' | (b) (4), (b) (6)            | 16 Feb 2021 15:35:15 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:13:32**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered '0'          | (b) (4), (b) (6)            | 16 Feb 2021 15:35:15 |



**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:13:32**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 16 Feb 2021 15:35:15 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:13:32**

**If not Ongoing, End date (*dd MMM yyyy*)**

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered '12 Feb 2021' | (b) (4), (b) (6)            | 16 Feb 2021 15:35:15 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:13:32**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 16 Feb 2021 15:35:15 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:13:32**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 16 Feb 2021 15:35:15 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:13:32**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 16 Feb 2021 15:35:15 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:13:32**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 16 Feb 2021 15:35:15 |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:13:32

Name of Medication

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                | 29 Apr 2021 13:49:25 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, PRODUCT: COUGH AND COLD PREPARATIONS - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4) | 20 Apr 2021 13:29:02 |
| 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) | 20 Apr 2021 13:29:02 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;EPHEDRINE SULFATE;ETHANOL;PARACETAMOL, PRODUCTSYNONYM: NYQUIL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 12 Apr 2021 11:40:52 |
| 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) | 12 Apr 2021 11:40:52 |
| User signature succeeded.  | Bindu Balani (b) (4)<br>(b) (4) | 11 Apr 2021 16:54:41 |
| Data point term sent to Coder  | System                          | 09 Apr 2021 14:11:55 |
| User closed query 'CDM Coding : Per query response, please update the term as NYQUIL (UNKNOWN) in the drug name field. Please make changes appropriately. Thank you.' (Site from System).  | System                          | 09 Apr 2021 14:11:54 |
| Query 'CDM Coding : Per query response, please update the term as NYQUIL (UNKNOWN) in the drug name field. Please make changes appropriately. Thank you.' answered with 'Term updated to NYQUIL (UNKNOWN) per query.' (Site from System).  | (b) (4), (b) (6)                | 09 Apr 2021 14:11:54 |
| Data point term sent to Coder  | System                          | 09 Apr 2021 14:11:52 |
| DataPoint Un-verified.   | (b) (4), (b) (6)                | 09 Apr 2021 14:11:16 |
| Coding entries removed.  | (b) (4), (b) (6)                | 09 Apr 2021 14:11:16 |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:13:32

Name of Medication

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| Signature has been broken.  | (b) (4), (b) (6)                | 09 Apr 2021 14:11:16 |
| User entered 'NYQUIL (UNKNOWN)' reason for change: Per Query Resolution   | (b) (4), (b) (6)                | 09 Apr 2021 14:11:16 |
| User opened query 'CDM Coding : Per query response, please update the term as NYQUIL (UNKNOWN) in the drug name field. Please make changes appropriately. Thank you.' (Site from System).   | Coder Import (b) (4)<br>(b) (4) | 09 Apr 2021 11:20:35 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;EPHEDRINE SULFATE;ETHANOL;PARACETAMOL, PRODUCTSYNONYM: NYQUIL - version WHODrug-Global-B3\202003.                         | Coder Import (b) (4)<br>(b) (4) | 07 Apr 2021 05:05:35 |
| 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) | 07 Apr 2021 05:05:35 |
| Data point term sent to Coder   | System                          | 06 Apr 2021 15:46:41 |
| User closed query 'For coding purposes, references indicate different formulations for NYQUIL Please provide generic ingredients, complete, accurate trade name and update the term with your response' (Site from System).   | System                          | 06 Apr 2021 15:45:44 |
| Query 'For coding purposes, references indicate different formulations for NYQUIL Please provide generic ingredients, complete, accurate trade name and update the term with your response' answered with 'Per source "Nyquil" was all that was given from subject to site. Thank you.' (Site from System). | (b) (4), (b) (6)                | 06 Apr 2021 15:45:44 |
| User opened query 'For coding purposes, references indicate different formulations for NYQUIL Please provide generic ingredients, complete, accurate trade name and update the term with your response' (Site from System).   | Coder Import (b) (4)<br>(b) (4) | 06 Apr 2021 15:01:49 |
| User signature succeeded.   | Bindu Balani (b) (4)<br>(b) (4) | 05 Apr 2021 21:29:37 |
| DataPoint Verified.   | (b) (4), (b) (6)                | 11 Mar 2021 15:29:50 |

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:13:32

[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: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;EPHEDRINE SULFATE;ETHANOL;PARACETAMOL, PRODUCTSYNONYM: NYQUIL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 16 Feb 2021 15:38:59 |
| 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) | 16 Feb 2021 15:38:59 |
| Data point term sent to Coder  | System                          | 16 Feb 2021 15:37:50 |
| User entered 'NYQUIL' reason for change: Data Entry Error  | (b) (4), (b) (6)                | 16 Feb 2021 15:37:41 |
| User entered 'Nyquil 2 tablespoons Q 12 hr x 3 doses - start 2/10 - stopped 2/12'  | (b) (4), (b) (6)                | 16 Feb 2021 15:37:34 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:32**

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 16 Feb 2021 15:37:34 |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:13:32

[Indication](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.   | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User closed query 'Per DM CLR: Note, there is no any corresponding data on Diary or AE that matches this Con Med indication during indicated timeframe. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' (Site from DM).   | (b) (4), (b) (6)            | 11 Mar 2021 03:50:43 |
| Query 'Per DM CLR: Note, there is no any corresponding data on Diary or AE that matches this Con Med indication during indicated timeframe. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' answered with 'Data was taken from source, documentation states that a visit follow-up phone call was made which occurred on February 9th, 2021- the same day the EUA vaccine # 2 was given to the subject. Medication "Tylenol" was taken to treat symptoms that the subject experienced after the injection. This information should have been captured in e-Diary. Thank you.' (Site from DM). | (b) (4), (b) (6)            | 10 Mar 2021 03:24:22 |
| User opened query 'Per DM CLR: Note, there is no any corresponding data on Diary or AE that matches this Con Med indication during indicated timeframe. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' (Site from DM).   | (b) (4), (b) (6)            | 09 Mar 2021 04:54:58 |
| User entered 'Fever 100.7'  | (b) (4), (b) (6)            | 16 Feb 2021 15:37:34 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:32**

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered '2'          | (b) (4), (b) (6)            | 16 Feb 2021 15:37:34 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:32**

[Dose unit](#)

| Audit                        | User                        | Time (GMT)           |
|------------------------------|-----------------------------|----------------------|
| User signature succeeded.    | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.          | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'Other (OTHER)' | (b) (4), (b) (6)            | 16 Feb 2021 15:37:34 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:32**

[If dose unit is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'tablespoon' | (b) (4), (b) (6)            | 16 Feb 2021 15:37:34 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:32**

[Frequency](#)

| Audit                        | User                        | Time (GMT)           |
|------------------------------|-----------------------------|----------------------|
| User signature succeeded.    | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.          | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'other (OTHER)' | (b) (4), (b) (6)            | 16 Feb 2021 15:37:34 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:32**

[If frequency is Other, specify](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'x q12 x 3 doses' | (b) (4), (b) (6)            | 16 Feb 2021 15:37:34 |



**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:32**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)            | 16 Feb 2021 15:37:34 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:32**

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 16 Feb 2021 15:37:34 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:32**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered '10 Feb 2021' | (b) (4), (b) (6)            | 16 Feb 2021 15:37:34 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:32**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered '0'          | (b) (4), (b) (6)            | 16 Feb 2021 15:37:34 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:32**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 16 Feb 2021 15:37:34 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:32**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered '12 Feb 2021' | (b) (4), (b) (6)            | 16 Feb 2021 15:37:34 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:32**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 16 Feb 2021 15:37:34 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:32**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 16 Feb 2021 15:37:34 |



**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:32**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 16 Feb 2021 15:37:34 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:13:32**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 16 Feb 2021 15:37:34 |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:13:32

Name of Medication

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)            | 05 Apr 2021 21:29:37 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)     | 11 Mar 2021 15:29:50 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: VALACICLOVIR HYDROCHLORIDE, PRODUCTSYNONYM: VALTREX - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 28 Feb 2021 17:44:28 |
| 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) | 28 Feb 2021 17:44:28 |
| Data point term sent to Coder  | System                          | 22 Feb 2021 20:47:25 |
| Data point term sent to Coder  | System                          | 22 Feb 2021 20:46:24 |
| User entered 'Valtrex (Valacyclovir Hydrochloride)' reason for change: New Information   | (b) (4), (b) (6)                | 22 Feb 2021 20:46:19 |
| Data point term sent to Coder  | System                          | 18 Feb 2021 20:29:41 |
| Data point term sent to Coder  | System                          | 18 Feb 2021 20:28:40 |
| Data point term sent to Coder  | System                          | 18 Feb 2021 20:10:17 |
| User entered 'Valacyclovir- Feb 9. 2021 x 3 weeks duration'  | (b) (4), (b) (6)                | 18 Feb 2021 20:09:53 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:13:32**

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 18 Feb 2021 20:09:53 |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:13:32

[Indication](#)

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| User signature succeeded.   | Bindu Balani (b) (4) | 05 Apr 2021 21:29:37 |
| DataPoint Verified.   | (b) (4)              |                      |
|   | (b) (4), (b) (6)     | 11 Mar 2021 15:29:50 |
| User entered 'PRESUMPTIVE SHINGLES' reason for change: New Information  | (b) (4), (b) (6)     | 22 Feb 2021 20:46:36 |
| User entered 'Presumptive Shingles- RASH TO SACRAL AREA (ITCHING AND BURNING SENSATION)' reason for change: New Information | (b) (4), (b) (6)     | 22 Feb 2021 20:46:19 |
| User entered 'HERPES ZOSTER RASH TO SACRAL AREA (itching and burning sensation)' reason for change: New Information         | (b) (4), (b) (6)     | 18 Feb 2021 20:28:53 |
| User entered 'HERPES ZOSTER rash to sacral area' reason for change: New Information   | (b) (4), (b) (6)     | 18 Feb 2021 20:28:07 |
| User entered 'Herpes zoster'  | (b) (4), (b) (6)     | 18 Feb 2021 20:09:53 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:13:32**

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'I'          | (b) (4), (b) (6)            | 18 Feb 2021 20:09:53 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:13:32**

[Dose unit](#)

| Audit                        | User                        | Time (GMT)           |
|------------------------------|-----------------------------|----------------------|
| User signature succeeded.    | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.          | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'Other (OTHER)' | (b) (4), (b) (6)            | 18 Feb 2021 20:09:53 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:13:32**

[If dose unit is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'gm'         | (b) (4), (b) (6)            | 18 Feb 2021 20:09:53 |



**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:13:32**

[Frequency](#)

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| User signature succeeded.   | Bindu Balani (b) (4) | 05 Apr 2021 21:29:37 |
| DataPoint Verified.   | (b) (4)              |                      |
|   | (b) (4), (b) (6)     | 11 Mar 2021 15:29:50 |
| User entered 'three times daily (TID)' reason for change: New Information | (b) (4), (b) (6)     | 22 Feb 2021 20:46:19 |
| User entered 'once daily (QD)'  | (b) (4), (b) (6)     | 18 Feb 2021 20:09:53 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:13:32**

[If frequency is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 18 Feb 2021 20:09:53 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:13:32**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)            | 18 Feb 2021 20:09:53 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:13:32**

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered empty.       | (b) (4), (b) (6)            | 18 Feb 2021 20:09:53 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:13:32**

[Start date \(dd MMM yyyy\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered '9 Feb 2021' | (b) (4), (b) (6)            | 18 Feb 2021 20:09:53 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:13:32**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered '0'          | (b) (4), (b) (6)            | 18 Feb 2021 20:09:53 |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:13:32

[Ongoing?](#)

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4) | 05 Apr 2021 21:29:37 |
| DataPoint Verified.  | (b) (4)              |                      |
|  | (b) (4), (b) (6)     | 11 Mar 2021 15:29:50 |
| User closed query 'Per progress note, stop date was 2/16/21. Please update data and add event to AE log page.' (Site from CRA).              | (b) (4), (b) (6)     | 11 Mar 2021 15:29:22 |
| Query 'Per progress note, stop date was 2/16/21. Please update data and add event to AE log page.' answered with 'Updated.' (Site from CRA). | (b) (4), (b) (6)     | 22 Feb 2021 20:46:43 |
| User entered 'No (N)' reason for change: New Information   | (b) (4), (b) (6)     | 22 Feb 2021 20:46:19 |
| User opened query 'Per progress note, stop date was 2/16/21. Please update data and add event to AE log page.' (Site from CRA).              | (b) (4), (b) (6)     | 22 Feb 2021 20:25:40 |
| User entered 'Yes (Y)'   | (b) (4), (b) (6)     | 18 Feb 2021 20:09:53 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:13:32**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.                                     | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered '16 Feb 2021' reason for change: New Information | (b) (4), (b) (6)            | 22 Feb 2021 20:46:19 |
| User entered empty.   | (b) (4), (b) (6)            | 18 Feb 2021 20:09:53 |



**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:13:32**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 15:29:50 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 18 Feb 2021 20:09:53 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:13:32**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '3' | System | 22 Feb 2021 20:46:19 |
| User entered '1' | System | 18 Feb 2021 20:09:53 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:13:32**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 18 Feb 2021 20:09:53 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:13:32**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 18 Feb 2021 20:09:53 |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:13:32

Name of Medication

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| User signature succeeded.   | Bindu Balani (b) (4)            | 02 May 2021 01:32:35 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4) | 27 Apr 2021 15:21:13 |
| 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) | 27 Apr 2021 15:21:13 |
| Data point term sent to Coder   | System                          | 27 Apr 2021 14:29:41 |
| User entered 'Vitamin D'  | (b) (4), (b) (6)                | 27 Apr 2021 14:29:05 |
| DataPoint activated with code reason code Data required.  | (b) (4), (b) (6)                | 27 Apr 2021 14:26:27 |
| DataPoint inactivated with code reason code Data not required.  | (b) (4), (b) (6)                | 22 Feb 2021 20:44:10 |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:13:32

[Prophylaxis](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                      | Bindu Balani (b) (4)        | 02 May 2021 01:32:35 |
| User entered 'Yes (Y)'   | (b) (4)<br>(b) (4), (b) (6) | 27 Apr 2021 14:29:05 |
| DataPoint activated with code reason code Data required.       | (b) (4), (b) (6)            | 27 Apr 2021 14:26:27 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)            | 22 Feb 2021 20:44:10 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:13:32**

[Indication](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                      | Bindu Balani (b) (4)        | 02 May 2021 01:32:35 |
| User entered 'Borderline low vitamin D deficiency'             | (b) (4)<br>(b) (4), (b) (6) | 27 Apr 2021 14:29:05 |
| DataPoint activated with code reason code Data required.       | (b) (4), (b) (6)            | 27 Apr 2021 14:26:27 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)            | 22 Feb 2021 20:44:10 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:13:32**

[Dose per administration](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                      | Bindu Balani (b) (4)        | 02 May 2021 01:32:35 |
| User entered '2000'  | (b) (4)<br>(b) (4), (b) (6) | 27 Apr 2021 14:29:05 |
| DataPoint activated with code reason code Data required.       | (b) (4), (b) (6)            | 27 Apr 2021 14:26:27 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)            | 22 Feb 2021 20:44:10 |



US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:13:32

[Dose unit](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                      | Bindu Balani (b) (4)        | 02 May 2021 01:32:35 |
| User entered 'IU (IU)'   | (b) (4)<br>(b) (4), (b) (6) | 27 Apr 2021 14:29:05 |
| DataPoint activated with code reason code Data required.       | (b) (4), (b) (6)            | 27 Apr 2021 14:26:27 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)            | 22 Feb 2021 20:44:10 |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:13:32

If dose unit is Other, specify

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| User signature succeeded.                                      | Bindu Balani (b) (4) | 02 May 2021 01:32:35 |
| User entered empty.  | (b) (4)              |                      |
|  | (b) (4), (b) (6)     | 27 Apr 2021 14:29:05 |
| DataPoint activated with code reason code Data required.       | (b) (4), (b) (6)     | 27 Apr 2021 14:26:27 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)     | 22 Feb 2021 20:44:10 |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:13:32

[Frequency](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                      | Bindu Balani (b) (4)        | 02 May 2021 01:32:35 |
| User entered 'once daily (QD)'                                 | (b) (4)<br>(b) (4), (b) (6) | 27 Apr 2021 14:29:05 |
| DataPoint activated with code reason code Data required.       | (b) (4), (b) (6)            | 27 Apr 2021 14:26:27 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)            | 22 Feb 2021 20:44:10 |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:13:32

If frequency is Other, specify

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| User signature succeeded.                                      | Bindu Balani (b) (4) | 02 May 2021 01:32:35 |
| User entered empty.  | (b) (4)              |                      |
|  | (b) (4), (b) (6)     | 27 Apr 2021 14:29:05 |
| DataPoint activated with code reason code Data required.       | (b) (4), (b) (6)     | 27 Apr 2021 14:26:27 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)     | 22 Feb 2021 20:44:10 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:13:32**

[Route of administration](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                      | Bindu Balani (b) (4)        | 02 May 2021 01:32:35 |
| User entered 'Oral (ORAL)'                                     | (b) (4)<br>(b) (4), (b) (6) | 27 Apr 2021 14:29:05 |
| DataPoint activated with code reason code Data required.       | (b) (4), (b) (6)            | 27 Apr 2021 14:26:27 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)            | 22 Feb 2021 20:44:10 |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:13:32

If route of administration is Other, specify

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| User signature succeeded.                                      | Bindu Balani (b) (4) | 02 May 2021 01:32:35 |
| User entered empty.  | (b) (4)              |                      |
|  | (b) (4), (b) (6)     | 27 Apr 2021 14:29:05 |
| DataPoint activated with code reason code Data required.       | (b) (4), (b) (6)     | 27 Apr 2021 14:26:27 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)     | 22 Feb 2021 20:44:10 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:13:32**

[Start date \(dd MMM yyyy\)](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                      | Bindu Balani (b) (4)        | 02 May 2021 01:32:35 |
| User entered '25 Apr 2021'                                     | (b) (4)<br>(b) (4), (b) (6) | 27 Apr 2021 14:29:05 |
| DataPoint activated with code reason code Data required.       | (b) (4), (b) (6)            | 27 Apr 2021 14:26:27 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)            | 22 Feb 2021 20:44:10 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:13:32**

[Start date completely unknown](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                      | Bindu Balani (b) (4)        | 02 May 2021 01:32:35 |
| User entered '0'   | (b) (4)<br>(b) (4), (b) (6) | 27 Apr 2021 14:29:05 |
| DataPoint activated with code reason code Data required.       | (b) (4), (b) (6)            | 27 Apr 2021 14:26:27 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)            | 22 Feb 2021 20:44:10 |



**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:13:32**

[Ongoing?](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                      | Bindu Balani (b) (4)        | 02 May 2021 01:32:35 |
| User entered 'Yes (Y)'   | (b) (4)<br>(b) (4), (b) (6) | 27 Apr 2021 14:29:05 |
| DataPoint activated with code reason code Data required.       | (b) (4), (b) (6)            | 27 Apr 2021 14:26:27 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)            | 22 Feb 2021 20:44:10 |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:13:32

If not Ongoing, End date (*dd MMM yyyy*)

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| User signature succeeded.                                      | Bindu Balani (b) (4) | 02 May 2021 01:32:35 |
| User entered empty.  | (b) (4)              |                      |
|  | (b) (4), (b) (6)     | 27 Apr 2021 14:29:05 |
| DataPoint activated with code reason code Data required.       | (b) (4), (b) (6)     | 27 Apr 2021 14:26:27 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)     | 22 Feb 2021 20:44:10 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:13:32**

[Was this medication taken for solicited event?](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                      | Bindu Balani (b) (4)        | 02 May 2021 01:32:35 |
| User entered 'No (N)'  | (b) (4)<br>(b) (4), (b) (6) | 27 Apr 2021 14:29:05 |
| DataPoint activated with code reason code Data required.       | (b) (4), (b) (6)            | 27 Apr 2021 14:26:27 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)            | 22 Feb 2021 20:44:10 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:13:32**

[Separate Dosage Number \(derived\)](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered 'I'   | System           | 27 Apr 2021 14:29:05 |
| DataPoint activated with code reason code Data required.       | (b) (4), (b) (6) | 27 Apr 2021 14:26:27 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6) | 22 Feb 2021 20:44:10 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:13:32**

[Interval Dosage Unit Number \(derived\)](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered '1'   | System           | 27 Apr 2021 14:29:05 |
| DataPoint activated with code reason code Data required.       | (b) (4), (b) (6) | 27 Apr 2021 14:26:27 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6) | 22 Feb 2021 20:44:10 |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:13:32

[Interval Dosage Definition \(derived\)](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered '804 (804)'                                       | System           | 27 Apr 2021 14:29:05 |
| DataPoint activated with code reason code Data required.       | (b) (4), (b) (6) | 27 Apr 2021 14:26:27 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6) | 22 Feb 2021 20:44:10 |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:13:32

[Name of Medication](#)

| Audit  | User                                       | Time (GMT)           |
|--|--|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)                       | 02 May 2021 01:32:35 |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: LIPID<br>MODIFYING AGENTS, ATC: LIPID MODIFYING<br>AGENTS, PLAIN, ATC: HMG COA REDUCTASE<br>INHIBITORS, PRODUCT: ROSUVASTATIN -<br>version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4)<br>(b) (4) | 27 Apr 2021 14:32:06 |
| 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)            | 27 Apr 2021 14:32:06 |
| Data point term sent to Coder  | System                                     | 27 Apr 2021 14:30:42 |
| User entered 'Rosuvastatin'  | (b) (4), (b) (6)                           | 27 Apr 2021 14:30:32 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:13:32**

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 02 May 2021 01:32:35 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 27 Apr 2021 14:30:32 |



**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:13:32**

[Indication](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                  | Bindu Balani (b) (4)        | 02 May 2021 01:32:35 |
| User entered 'Borderline high cholesterol' | (b) (4)<br>(b) (4), (b) (6) | 27 Apr 2021 14:30:32 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:13:32**

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 02 May 2021 01:32:35 |
| User entered '5'          | (b) (4)<br>(b) (4), (b) (6) | 27 Apr 2021 14:30:32 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:13:32**

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 02 May 2021 01:32:35 |
| User entered 'mg (mg)'    | (b) (4)<br>(b) (4), (b) (6) | 27 Apr 2021 14:30:32 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:13:32**

[If dose unit is Other, specify](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4) | 02 May 2021 01:32:35 |
|                           | (b) (4)              |                      |
| User entered empty.       | (b) (4), (b) (6)     | 27 Apr 2021 14:30:32 |
|                           |                      |                      |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:13:32**

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Bindu Balani (b) (4)        | 02 May 2021 01:32:35 |
| User entered 'once daily (QD)' | (b) (4)<br>(b) (4), (b) (6) | 27 Apr 2021 14:30:32 |

US3602123

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:13:32

If frequency is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 02 May 2021 01:32:35 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 27 Apr 2021 14:30:32 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:13:32**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 02 May 2021 01:32:35 |
| User entered 'Oral (ORAL)' | (b) (4)<br>(b) (4), (b) (6) | 27 Apr 2021 14:30:32 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:13:32**

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 02 May 2021 01:32:35 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 27 Apr 2021 14:30:32 |



**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:13:32**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Bindu Balani (b) (4)        | 02 May 2021 01:32:35 |
| User entered '25 Apr 2021' | (b) (4)<br>(b) (4), (b) (6) | 27 Apr 2021 14:30:32 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:13:32**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 02 May 2021 01:32:35 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 27 Apr 2021 14:30:32 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:13:32**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 02 May 2021 01:32:35 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 27 Apr 2021 14:30:32 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:13:32**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 02 May 2021 01:32:35 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 27 Apr 2021 14:30:32 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:13:32**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 02 May 2021 01:32:35 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 27 Apr 2021 14:30:32 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:13:32**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 27 Apr 2021 14:30:32 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:13:32**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 27 Apr 2021 14:30:32 |

**US3602123**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:13:32**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 27 Apr 2021 14:30:32 |



US3602123

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:13:32

[Were any concomitant procedures performed?](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 03 May 2021 08:46:18 |
| User signature succeeded.                                 | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered 'Yes (Y)' reason for change: New Information | (b) (4)<br>(b) (4), (b) (6) | 19 Mar 2021 21:54:30 |
| User entered 'No (N)'                                     | (b) (4), (b) (6)            | 02 Oct 2020 20:41:58 |

**US3602123**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:13:32**

**Procedure/Surgery date (dd MMM yyyy)**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered '9 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 19 Mar 2021 21:54:50 |

**US3602123**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Procedure/Surgery](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered 'Blood work' | (b) (4)<br>(b) (4), (b) (6) | 19 Mar 2021 21:54:50 |

**US3602123**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Indication](#)

| Audit                             | User                        | Time (GMT)           |
|-----------------------------------|-----------------------------|----------------------|
| User signature succeeded.         | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered 'Adverse Event (AE)' | (b) (4)<br>(b) (4), (b) (6) | 19 Mar 2021 21:54:50 |

US3602123

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:13:32

If indication is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 19 Mar 2021 21:54:50 |

**US3602123**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 09:13:32**

**Procedure/Surgery date (dd MMM yyyy)**

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 01 May 2021 13:05:47 |
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered '12 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 19 Mar 2021 21:55:09 |

**US3602123**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Procedure/Surgery](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 13:05:47 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered 'Blood work' | (b) (4)<br>(b) (4), (b) (6) | 19 Mar 2021 21:55:09 |

**US3602123**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Indication](#)

| Audit                             | User                        | Time (GMT)           |
|-----------------------------------|-----------------------------|----------------------|
| Data hard locked.                 | (b) (4), (b) (6)            | 01 May 2021 13:05:47 |
| User signature succeeded.         | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered 'Adverse Event (AE)' | (b) (4)<br>(b) (4), (b) (6) | 19 Mar 2021 21:55:09 |



**US3602123**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 09:13:32**

[If indication is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 13:05:47 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 19 Mar 2021 21:55:09 |

**US3602123**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 10 Jun 2021 09:13:32**

**Procedure/Surgery date (dd MMM yyyy)**

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 01 May 2021 13:05:50 |
| User signature succeeded.  | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered '15 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 19 Mar 2021 21:55:43 |

**US3602123**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 10 Jun 2021 09:13:32**

[Procedure/Surgery](#)

| Audit                        | User                        | Time (GMT)           |
|------------------------------|-----------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)            | 01 May 2021 13:05:50 |
| User signature succeeded.    | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered 'Blood work-up' | (b) (4)<br>(b) (4), (b) (6) | 19 Mar 2021 21:55:43 |

**US3602123**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 10 Jun 2021 09:13:32**

[Indication](#)

| Audit                             | User                        | Time (GMT)           |
|-----------------------------------|-----------------------------|----------------------|
| Data hard locked.                 | (b) (4), (b) (6)            | 01 May 2021 13:05:50 |
| User signature succeeded.         | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered 'Adverse Event (AE)' | (b) (4)<br>(b) (4), (b) (6) | 19 Mar 2021 21:55:43 |

**US3602123**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 10 Jun 2021 09:13:32**

[If indication is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 13:05:50 |
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:29:37 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 19 Mar 2021 21:55:43 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.                             | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.                                   | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.                                  | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered<br>'USA-US079-2021-MRNA-1273-P301000002' | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

**Serious**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'Yes (Y)'    | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |



**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'Yes (Y)'    | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'Bindu'      | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'Balani'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Site Address: State](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'NJ'         | System                      | 17 Feb 2021 14:54:54 |



**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 15:18:02 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 18 Feb 2021 18:34:19 |
| User entered 'US'         | System                      | 17 Feb 2021 14:55:31 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '8' | System | 22 Mar 2021 18:46:21 |
| User entered '7' | System | 17 Mar 2021 19:52:25 |
| User entered '6' | System | 10 Mar 2021 15:41:21 |
| User entered '5' | System | 09 Mar 2021 14:24:51 |
| User entered '4' | System | 01 Mar 2021 14:38:48 |
| User entered '3' | System | 26 Feb 2021 15:54:18 |
| User entered '2' | System | 23 Feb 2021 15:17:58 |
| User entered '1' | System | 17 Feb 2021 14:55:31 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.                             | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.                                   | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.                                  | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered<br>'USA-US079-2021-MRNA-1273-P301000002' | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

**Serious**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'Yes (Y)'    | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |



**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'Yes (Y)'    | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'Bindu'      | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'Balani'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Site Address: State](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'NJ'         | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 15:18:02 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 18 Feb 2021 18:34:19 |
| User entered 'US'         | System                      | 17 Feb 2021 14:55:31 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '8' | System | 22 Mar 2021 18:46:21 |
| User entered '7' | System | 17 Mar 2021 19:52:25 |
| User entered '6' | System | 10 Mar 2021 15:41:21 |
| User entered '5' | System | 09 Mar 2021 14:24:51 |
| User entered '4' | System | 01 Mar 2021 14:38:48 |
| User entered '3' | System | 26 Feb 2021 15:54:18 |
| User entered '2' | System | 23 Feb 2021 15:17:58 |
| User entered '1' | System | 17 Feb 2021 14:55:31 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:13:32**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                        | Time (GMT)           |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded.        | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.              | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| User entered '17/Feb/2021 09:55' | System                      | 17 Feb 2021 14:55:31 |



US3602123

Folder: SAE USA-US079-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:13:32

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
| Reviewed for Safety.      | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 23 Feb 2021 15:18:02 |
| DataPoint Verified.       | (b) (4), (b) (6)     | 18 Feb 2021 18:34:19 |
| User entered 'I'          | (b) (4), (b) (6)     | 17 Feb 2021 14:55:31 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.                             | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.                                   | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.                                  | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered<br>'USA-US079-2021-MRNA-1273-P301000002' | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

**Serious**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'Yes (Y)'    | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |



**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'Yes (Y)'    | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'Bindu'      | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'Balani'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Site Address: State](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'NJ'         | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 15:18:02 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 18 Feb 2021 18:34:19 |
| User entered 'US'         | System                      | 17 Feb 2021 14:55:31 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '8' | System | 22 Mar 2021 18:46:21 |
| User entered '7' | System | 17 Mar 2021 19:52:25 |
| User entered '6' | System | 10 Mar 2021 15:41:21 |
| User entered '5' | System | 09 Mar 2021 14:24:51 |
| User entered '4' | System | 01 Mar 2021 14:38:48 |
| User entered '3' | System | 26 Feb 2021 15:54:18 |
| User entered '2' | System | 23 Feb 2021 15:17:58 |
| User entered '1' | System | 17 Feb 2021 14:55:31 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:13:32**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                 | Time (GMT)           |
|----------------------------------|----------------------|----------------------|
| User signature succeeded.        | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
| User entered '23/Feb/2021 10:17' | (b) (4)<br>System    | 23 Feb 2021 15:17:58 |

US3602123

Folder: SAE USA-US079-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:13:32

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
| Reviewed for Safety.      | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 23 Feb 2021 15:18:02 |
| User entered 'I'          | (b) (4), (b) (6)     | 23 Feb 2021 15:17:58 |



**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.                             | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.                                   | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.                                  | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered<br>'USA-US079-2021-MRNA-1273-P301000002' | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

**Serious**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'Yes (Y)'    | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'Yes (Y)'    | System                      | 17 Feb 2021 14:54:54 |



**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'Bindu'      | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'Balani'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Site Address: State](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'NJ'         | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 15:18:02 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 18 Feb 2021 18:34:19 |
| User entered 'US'         | System                      | 17 Feb 2021 14:55:31 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '8' | System | 22 Mar 2021 18:46:21 |
| User entered '7' | System | 17 Mar 2021 19:52:25 |
| User entered '6' | System | 10 Mar 2021 15:41:21 |
| User entered '5' | System | 09 Mar 2021 14:24:51 |
| User entered '4' | System | 01 Mar 2021 14:38:48 |
| User entered '3' | System | 26 Feb 2021 15:54:18 |
| User entered '2' | System | 23 Feb 2021 15:17:58 |
| User entered '1' | System | 17 Feb 2021 14:55:31 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 09:13:32**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                 | Time (GMT)           |
|----------------------------------|----------------------|----------------------|
| User signature succeeded.        | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
| User entered '26/Feb/2021 10:54' | (b) (4)<br>System    | 26 Feb 2021 15:54:18 |

US3602123

Folder: SAE USA-US079-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:13:32

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 01 Mar 2021 14:39:12 |
| User entered 'I'          | (b) (4), (b) (6)            | 26 Feb 2021 15:54:18 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.                             | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.                                   | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.                                  | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered<br>'USA-US079-2021-MRNA-1273-P301000002' | System                      | 17 Feb 2021 14:54:54 |



**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

**Serious**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'Yes (Y)'    | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'Yes (Y)'    | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'Bindu'      | System                      | 17 Feb 2021 14:54:54 |



**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'Balani'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Site Address: State](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'NJ'         | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 15:18:02 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 18 Feb 2021 18:34:19 |
| User entered 'US'         | System                      | 17 Feb 2021 14:55:31 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '8' | System | 22 Mar 2021 18:46:21 |
| User entered '7' | System | 17 Mar 2021 19:52:25 |
| User entered '6' | System | 10 Mar 2021 15:41:21 |
| User entered '5' | System | 09 Mar 2021 14:24:51 |
| User entered '4' | System | 01 Mar 2021 14:38:48 |
| User entered '3' | System | 26 Feb 2021 15:54:18 |
| User entered '2' | System | 23 Feb 2021 15:17:58 |
| User entered '1' | System | 17 Feb 2021 14:55:31 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 09:13:32**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                 | Time (GMT)           |
|----------------------------------|----------------------|----------------------|
| User signature succeeded.        | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
| User entered '01/Mar/2021 09:38' | (b) (4)<br>System    | 01 Mar 2021 14:38:48 |

US3602123

Folder: SAE USA-US079-2021-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:13:32

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
| Reviewed for Safety.      | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 01 Mar 2021 14:39:12 |
| User entered 'I'          | (b) (4), (b) (6)     | 01 Mar 2021 14:38:48 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.                             | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.                                   | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.                                  | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered<br>'USA-US079-2021-MRNA-1273-P301000002' | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

**Serious**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'Yes (Y)'    | System                      | 17 Feb 2021 14:54:54 |



**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'Yes (Y)'    | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'Bindu'      | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'Balani'     | System                      | 17 Feb 2021 14:54:54 |



**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Site Address: State](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'NJ'         | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 15:18:02 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 18 Feb 2021 18:34:19 |
| User entered 'US'         | System                      | 17 Feb 2021 14:55:31 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '8' | System | 22 Mar 2021 18:46:21 |
| User entered '7' | System | 17 Mar 2021 19:52:25 |
| User entered '6' | System | 10 Mar 2021 15:41:21 |
| User entered '5' | System | 09 Mar 2021 14:24:51 |
| User entered '4' | System | 01 Mar 2021 14:38:48 |
| User entered '3' | System | 26 Feb 2021 15:54:18 |
| User entered '2' | System | 23 Feb 2021 15:17:58 |
| User entered '1' | System | 17 Feb 2021 14:55:31 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form (5)**

**Generated On: 10 Jun 2021 09:13:32**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                 | Time (GMT)           |
|----------------------------------|----------------------|----------------------|
| User signature succeeded.        | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
| User entered '09/Mar/2021 06:24' | (b) (4)<br>System    | 09 Mar 2021 14:24:51 |

US3602123

Folder: SAE USA-US079-2021-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:13:32

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 15:41:29 |
| User entered 'I'          | (b) (4), (b) (6)            | 09 Mar 2021 14:24:51 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.                             | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.                                   | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.                                  | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered<br>'USA-US079-2021-MRNA-1273-P301000002' | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

**Serious**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'Yes (Y)'    | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |



**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'Yes (Y)'    | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'Bindu'      | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'Balani'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Site Address: State](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'NJ'         | System                      | 17 Feb 2021 14:54:54 |



**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 15:18:02 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 18 Feb 2021 18:34:19 |
| User entered 'US'         | System                      | 17 Feb 2021 14:55:31 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '8' | System | 22 Mar 2021 18:46:21 |
| User entered '7' | System | 17 Mar 2021 19:52:25 |
| User entered '6' | System | 10 Mar 2021 15:41:21 |
| User entered '5' | System | 09 Mar 2021 14:24:51 |
| User entered '4' | System | 01 Mar 2021 14:38:48 |
| User entered '3' | System | 26 Feb 2021 15:54:18 |
| User entered '2' | System | 23 Feb 2021 15:17:58 |
| User entered '1' | System | 17 Feb 2021 14:55:31 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form (6)**

**Generated On: 10 Jun 2021 09:13:32**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                 | Time (GMT)           |
|----------------------------------|----------------------|----------------------|
| User signature succeeded.        | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
| User entered '10/Mar/2021 10:41' | (b) (4)<br>System    | 10 Mar 2021 15:41:21 |

US3602123

Folder: SAE USA-US079-2021-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:13:32

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 15:41:29 |
| User entered 'I'          | (b) (4), (b) (6)            | 10 Mar 2021 15:41:21 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.                             | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.                                   | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.                                  | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered<br>'USA-US079-2021-MRNA-1273-P301000002' | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

**Serious**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'Yes (Y)'    | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |



**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'Yes (Y)'    | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'Bindu'      | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'Balani'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Site Address: State](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'NJ'         | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 15:18:02 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 18 Feb 2021 18:34:19 |
| User entered 'US'         | System                      | 17 Feb 2021 14:55:31 |



**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '8' | System | 22 Mar 2021 18:46:21 |
| User entered '7' | System | 17 Mar 2021 19:52:25 |
| User entered '6' | System | 10 Mar 2021 15:41:21 |
| User entered '5' | System | 09 Mar 2021 14:24:51 |
| User entered '4' | System | 01 Mar 2021 14:38:48 |
| User entered '3' | System | 26 Feb 2021 15:54:18 |
| User entered '2' | System | 23 Feb 2021 15:17:58 |
| User entered '1' | System | 17 Feb 2021 14:55:31 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form (7)**

**Generated On: 10 Jun 2021 09:13:32**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                 | Time (GMT)           |
|----------------------------------|----------------------|----------------------|
| User signature succeeded.        | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
| User entered '17/Mar/2021 15:52' | (b) (4)<br>System    | 17 Mar 2021 19:52:25 |

US3602123

Folder: SAE USA-US079-2021-MRNA-1273-P301000002

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:13:32

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 22 Mar 2021 18:46:08 |
| User entered 'I'          | (b) (4), (b) (6)            | 17 Mar 2021 19:52:25 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.                             | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.                                   | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.                                  | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered<br>'USA-US079-2021-MRNA-1273-P301000002' | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

**Serious**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'Yes (Y)'    | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |



**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'No (N)'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'Yes (Y)'    | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'Bindu'      | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'Balani'     | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Site Address: State](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 18:34:19 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 17 Feb 2021 14:55:19 |
| User entered 'NJ'         | System                      | 17 Feb 2021 14:54:54 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 15:18:02 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 18 Feb 2021 18:34:19 |
| User entered 'US'         | System                      | 17 Feb 2021 14:55:31 |

**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:13:32**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '8' | System | 22 Mar 2021 18:46:21 |
| User entered '7' | System | 17 Mar 2021 19:52:25 |
| User entered '6' | System | 10 Mar 2021 15:41:21 |
| User entered '5' | System | 09 Mar 2021 14:24:51 |
| User entered '4' | System | 01 Mar 2021 14:38:48 |
| User entered '3' | System | 26 Feb 2021 15:54:18 |
| User entered '2' | System | 23 Feb 2021 15:17:58 |
| User entered '1' | System | 17 Feb 2021 14:55:31 |



**US3602123**

**Folder: SAE USA-US079-2021-MRNA-1273-P301000002**

**Form: Safety Report Form (8)**

**Generated On: 10 Jun 2021 09:13:32**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                 | Time (GMT)           |
|----------------------------------|----------------------|----------------------|
| User signature succeeded.        | Bindu Balani (b) (4) | 05 Apr 2021 21:30:07 |
| User entered '22/Mar/2021 14:46' | (b) (4)<br>System    | 22 Mar 2021 18:46:21 |

US3602123

Folder: SAE USA-US079-2021-MRNA-1273-P301000002

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:13:32

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bindu Balani (b) (4)        | 05 Apr 2021 21:30:07 |
| User entered 'I'          | (b) (4)<br>(b) (4), (b) (6) | 22 Mar 2021 18:46:21 |